EXHIBIT

Discovery Referenced in Notice

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	MDL No. 2419
	)	Dkt. No. 1:13-md-2419-RWZ
This Document Relates to Suits Naming:	)	
Suits Naming the Tennessee Clinic Defendants	)	

THE TENNESSEE CLINIC DEFENDANTS' FIRST INTERROGATORIES, REQUESTS FOR PRODUCTON OF DOCUMENTS, AND REQUESTS FOR ADMISSION PROPOUNDED TO BARRY CADDEN.

Come the Defendants, Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants") , pursuant to Rules 26, 33, and 34 of the Federal Rules of Civil Procedure and the Local Rules for the District of Massachusetts, and propound the following Interrogatories, Requests for Production of Documents, and Requests for Admission to Barry Cadden.

Each of the following Interrogatories shall be answered under oath, in writing, separately, to the fullest possible detail, and in accordance with the definitions and instructions set forth below. The answers shall be signed by the person making them, and a copy of the answers, together with objections, if any, shall be served within thirty (30) days after the service date of these Interrogatories.

You are under a duty to seasonably supplement your response with respect to any Interrogatory directly addressed to the identity and location of persons having knowledge of discoverable matters. You are under a duty to amend a prior response if you obtain information on the basis of which you know that the response was incorrect when made, or that the response, though correctly made, is no longer true, and the circumstances are such that a failure to amend the response is, in substance, a knowing concealment.

DEFINITIONS

1. As used in this document, the terms "person(s)" and "individual(s)" mean any natural individual in any capacity whatsoever or any entity or organization, including divisions, departments, and other units therein, and shall include, but not be limited to, a public or private corporation, partnership, joint venture, voluntary or unincorporated association, organization, proprietorship, trust, estate, governmental agency, commission, bureau, or department.

2. As used in this document, the term "document" means any medium upon which intelligence or information can be recorded or retrieved, and includes without limitation, the original and each copy, regardless of origin and location, of any book, pamphlet, periodical, letter, memorandum (including any memorandum or report of a meeting or conversation), invoice, bill, order form, receipt, financial statement, accounting entry, diary, calendar, telex, telegram, cable, report, record, contract, agreement, study, handwritten note, draft, working paper, chart, paper, print, laboratory record, drawing or sketch, graph, index, lists, tape, photograph, microfilm, data sheet or data processing card, or any other written, recorded, transcribed, punched, taped, filmed, or graphic matter, however produced or reproduced, which is in your possession, custody, or control, or which was, but is no longer, in your possession, custody, or control.

3. As used in this document, the terms "identification," "identify," or "identity," when used in reference to a natural individual, require you to state his or her full name and residential and business address. Use of the term "document" in connection with the Interrogatories requires you to state the number of pages and the nature of the document, its title, its date, the name or names of its authors, and recipients, and its present location and custodian.

4. "You" and "your" refers to Barry Cadden and each of his present and former agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on his behalf.

5. "Communication" means any oral or written utterance, notification, or statement of any nature whatsoever, by and to whomsoever made, including, but not limited to, correspondence, conversation, dialogue, discussions, interviews, consultants, and any other understanding between or among two or more persons.

INSTRUCTIONS

1. With respect to each Interrogatory, in addition to answering the question, you are to identify all documents that support, refer to, or evidence the subject matter of each Interrogatory and your answer thereto.

   If any or all identified documents are no longer in your possession, custody, or control because of destruction, loss, or any other reason, then you must do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and the copy of the document;

   D. State in as much detail as possible the contents of the documents; and

   E. State the manner and date of disposition of the document.

   If you contend that you are entitled to withhold from production any or all documents identified herein on the basis of attorney-client privilege, the work-product doctrine, or any other ground, then do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and a copy of the document;

   D. State the subject matter of the document; and

   E. State the basis upon which you contend you are entitled to withhold the document from production.

2. All documents produced should be organized and labeled to correspond to the specific Request in response to which they are being made available or should be produced as they are kept in the usual course of business.

3. The terms "and," "or," and "and/or" should be construed either disjunctively or conjunctively so as to bring within the scope of these Interrogatories and Requests any information that might otherwise be construed as outside their scope.

4. The term "any" should be construed to include the word "all," and "all" should be construed to include "any."

5. The present tense should be construed to include the past tense, and the past tense should be construed to include the present tense.

6. The singular should be construed to include the plural, and the plural should be construed to include the singular.

7. The terms "he" and "his" should be construed to include the words "she" and "her" or "hers," respectively and vice versa.

8. "Relating to," when referring to a document shall mean mentioning, describing, connected to or with, or discussing the stated subject matter.

INTERROGATORIES

On March 18, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to Barry Cadden.* In order to minimize the impact of discovery on Barry Cadden, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Interrogatories 1-6** from the *Saint Thomas Entities' First Set of Interrogatories.* The "new" interrogatories begin at Number 7.

1-6. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Interrogatories 1-11 from the *Saint Thomas Entities' First Set of Interrogatories.*]

ANSWER:

7. Describe in detail your role at NECC and Ameridose, including job title, job description, and a description of your daily duties and activities in 2011 and 2012.

ANSWER:

8. Describe in detail the steps NECC took to compound, process, stopper, seal, package, and ship methylprednisolone acetate ("MPA") in 2011 and 2012, including but not limited to:

a) The names and job titles of the individuals performing each step;

b) The specific cleanroom or location in NECC's facility where each step took place;

c) The tools, equipment, or machinery used for each step;

d) Any changes to NECC's methods or procedures for compounding MPA, or the location where compounding MPA took place, that occurred in 2011 or 2012.

ANSWER:

9. Identify the total amount of MPA that NECC, and separately Ameridose, produced in each quarter of 2010, 2011, and 2012.

ANSWER:

10. Identify the types of vials and closures NECC used for MPA lots numbered 052122012@68, 06292012@26, and 08102012@51 (collectively "Contaminated Lots"), including whether the vials and enclosures were prewashed or presterilized, and identify their manufacturer(s) and from whom they were purchased by NECC.

ANSWER:

11. Identify any and all complaints that NECC and Ameridose received related to the sterility or safety of their products, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER:

12. Identify any customers of NECC and Ameridose who performed site visits prior to placing orders with either company.

ANSWER:

13. Describe any policies, procedures, or protocols relating to or regarding customer site visits to the NECC facility, including the areas you allowed customers to inspect.

ANSWER:

14. Identify any customers who took the following actions prior to placing orders with NECC or Ameridose:

    a. Verified whether NECC's quality processes demonstrated that NECC was a reputable and safe supplier of sterile injectable compounds;

    b. Determined if NECC was an accredited compounding pharmacy;

    c. At least once annually, unannounced, visited NECC's corporate offices and compounding facilities and conferred with NECC's corporate, pharmacy, and compounding staff;

    d. Determined whether NECC had any product liability lawsuits filed against it for preparations compounded;

    e. Determined whether there had ever been recalls of any of NECC's compounded preparations;

    f. Evaluated NECC's standard operating procedures and manuals;

    g. Evaluated NECC's pharmacist technician training;

    h. Evaluated NECC's policies and procedures for sterility testing;

i. Evaluated examples of batch reports for product being considered for outsourcing;

j. Evaluated examples of quality-control reports;

k. Obtained and evaluated history of the results of all NECC accreditation or regulatory surveys conducted of NECC's sites, including copies of significant regulatory actions;

l. Determined if NECC could provide documentation of the end-product testing processes used to determine that compounded sterile preparations are sterile and free of pyrogens and unintended particulate matter;

m. Evaluated whether NECC could assure that each compounded sterile preparation was sterile and free of pyrogens and unintended particulate matter according to professional established and accepted quality monitoring data;

n. Determined whether NECC performed nonviable and viable particle testing in primary engineering controls (e.g., laminar flow workbench, biological safety cabinet) and room air according to USP chapter 797 standards;

o. Determined whether NECC performed routine surface microbiological and fungal environmental monitoring to minimize contamination;

p. Determined whether NECC had a policy that required validation of new or changed facilities, equipment, processes, or container types, for sterility and repeatability;

q. Determined whether NECC met ASHP, NIOSH and USP chapter 797 guidelines for the handling of hazardous agents;

r. Evaluated NECC's quality management program, specifically as it relates to facility cleaning and validation, staff training, and competency assessment;

s. Evaluated NECC's risk assessment program to ensure that medication errors are not introduced by new or increased outsourced compounding activities; or

t. Determined whether NECC had a history of disciplinary or punitive actions by any regulatory agency.

ANSWER:

15. Describe any information you, NECC, or Ameridose provided to each customer in response to the inquiries identified in the previous Interrogatory.

ANSWER:

16. Identify any and all complaints NECC or Ameridose received related to their compliance with state or federal laws and regulations, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER:

17. Identify and describe any way in which NECC's cleanrooms were modified, altered, or expanded by NECC or Ameridose.

ANSWER:

18. Identify any policies, procedures, or guidelines in place at NECC in 2012 that encouraged employees to disclose mistakes in the compounding process, even if the mistakes necessitated destruction of product or halting production.

ANSWER:

19. Describe all disciplinary or enforcement action taken against NECC or Ameridose by any state or federal government agency.

ANSWER:

20. Describe in detail Lisa Conigliaro Cadden's role at NECC in 2011 and 2012.

ANSWER:

VERIFICATION

STATE OF TENNESSEE)
)
COUNTY OF _____)

I, _____, after being duly sworn, hereby make oath that the foregoing answers to interrogatories are true to the best of my knowledge, information, and belief.

_____

Sworn to and subscribed before me this _____ day of _____, 2015.

_____
Notary Public

My commission expires on: _____.

REQUESTS FOR PRODUCTION

On March 18, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to Barry Cadden.* In order to minimize the impact of discovery on Barry Cadden, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Requests for Production 1-39** from the *Saint Thomas Entities' First Requests for Production.* The "new" requests begin at Number 40.

1-39. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Requests for Production 1-39 from the *Saint Thomas Entities' First Requests for Production.*]

RESPONSE:

40. Produce all correspondence between you and any of the Tennessee Clinic Defendants, their employees, agents, or representatives.

RESPONSE:

41. Produce all correspondence and documents referring or relating to the Tennessee Clinic Defendants' purchase of MPA from NECC in 2011 or 2012.

RESPONSE:

42. Produce all documents produced by the government to you during any civil, criminal, or administrative proceedings related to NECC's contaminated MPA.

RESPONSE:

43. Produce all policies, procedures, guidelines, instructions and training documents referring or relating to the compounding of MPA at the NECC facility.

RESPONSE:

44. Produce all documents referring or relating to NECC or Ameridose sending sufficient samples, by size or volume, to comply with USP 71 to ARL or any other testing laboratory.

RESPONSE:

45. Produce all correspondence and documents referring or relating to fungal blooms or growth in or near NECC's cleanrooms.

RESPONSE:

46. Produce all documents referring or relating to any complaints that NECC or Ameridose received related to the sterility or safety of their products, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

47. Produce all documents referring or relating to any complaints NECC or Ameridose received related to their compliance with state or federal laws and regulations, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

48. Produce all correspondence and documents referring or relating to NECC's response to the meningitis outbreak, including but not limited to, steps NECC took to prepare for any inspections of its facility.

RESPONSE:

49. Produce all training and instructional material for sales staff at NECC or MSM.

RESPONSE:

REQUESTS FOR ADMISSION

On March 18, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to Barry Cadden.* In order to minimize the impact of discovery on Barry Cadden, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Requests for Admission 1-16** from the *Saint Thomas Entities' First Requests for Admission.* The "new" requests begin at Number 17.

1-16. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Requests for Admission 1-16 from the *Saint Thomas Entities' First Requests for Admission.*]

ANSWER:

17. Admit that you were NECC's pharmacist in charge in 2011 and 2012.

ANSWER:

18. Admit that you signed NECC's application for a pharmacy license in Tennessee representing yourself to be NECC's pharmacist in charge.

ANSWER:

19. Admit that on December 6, 2004, the Tennessee Board of Pharmacy granted you pharmacist license number 22971, permitting you to practice as a pharmacist in the state of Tennessee.

ANSWER:

20. Admit that on or about October 12, 2012, NECC executed a Voluntary Surrender Agreement in which it voluntarily surrendered its license to practice pharmacy in the state of Tennessee.

ANSWER:

21. Admit that on or about October 20, 2012, you executed a Voluntary Surrender Agreement in which you voluntarily surrendered your license to practice as a pharmacist in the state of Tennessee.

ANSWER:

22. Admit that as the pharmacist in charge at NECC, you had the authority and responsibility for compliance with the laws and rules pertaining to the practice of pharmacy of NECC at its practice site.

ANSWER:

23. Admit that as NECC's pharmacist in charge, you were responsible for the duties set forth in Tenn. Comp. R & Regs. No. 1140-7-.02 and Tenn. Comp. R & Regs. No. 1140-03-.14

ANSWER:

24. Admit that, had any of the Tennessee Clinic Defendants asked for a copy of NECC's license in 2011, you would have provided a valid and up-to-date Tennessee pharmacy license.

ANSWER:

25. Admit that NECC represented to potential customers, including the Tennessee Clinic Defendants, that it met or exceeded USP 797 standards.

ANSWER:

26. Admit that NECC represented to potential customers, including the Tennessee Clinic Defendants, that its products, including MPA, were safe and sterile.

ANSWER:

27. Admit that the Massachusetts Board of Pharmacy ("Mass. BoP") inspected NECC on or about May 24, 2011.

ANSWER:

28. Admit that as a result of its inspection on or about May 24, 2011 the Mass. BoP issued an inspection report documenting its findings.

ANSWER:

29. Admit that you did not submit a copy of the Mass. BoP's May 24, 2011 inspection report to the Tennessee Board of Pharmacy.

ANSWER:

30. Admit that you owed a duty to the Plaintiffs to ensure that NECC's MPA was sterile prior to distributing it to customers.

ANSWER:

31. Admit that the documents attached as Exhibit A are NECC's Logged Formula Worksheets for the MPA lots numbered 052122012@68, 06292012@26, and 08102012@51 (collectively "Contaminated Lots").

ANSWER:

32. Admit that in each Logged Formula Worksheet in Exhibit A, the pharmacist referred to as "GC" is Glenn Chin.

ANSWER:

33. Admit that the Logged Formula Worksheet for lot 06292012@26, attached as Exhibit B, states that the MPA was autoclaved for twenty (20) minutes at 121 C. and 15 PSI.

ANSWER:

34. Admit that NECC's Standard Operating Procedures required that the MPA be autoclaved for fifteen (15) minutes at 121 C. and 15 PSI.

ANSWER:

35. Admit that the Logged Formula Worksheets in Exhibit B state that Joseph P. Connolly was the technician for MPA lots 052122012@68 and 06292012@26.

ANSWER:

36. Admit that Glenn Chin compounded lot 08102012@51.

ANSWER:

37. Admit that Glenn Chin and Joseph Connolly compounded lots 052122012@68 and 06292012@26@51.

ANSWER:

38. Admit that NECC violated its own standard operating procedures by permitting Joseph Connolly (a technician) to compound two of the three contaminated lots.

ANSWER:

39. Admit that Exhibit C is NECC's General Overview of Policies & Procedures for Compounding Sterile Products.

ANSWER:

40. Admit that Exhibit C states, in part:

C. Personnel

a. All sterile compounding is performed by properly trained and validated pharmacists (*no* technicians).

ANSWER:

41. Admit that the documents attached as Exhibit D are reports from Analytical Research Laboratories ("ARL") related to the sterility and endotoxin testing ARL performed on NECC's MPA from the Contaminated Lots.

ANSWER:

42. Admit that NECC submitted only two 5 mL vials of MPA from each of the Contaminated Lots to ARL for testing.

ANSWER:

43. Admit that USP standards for sterility testing required a larger sample size than two 5 mL vials per lot of MPA.

ANSWER:

44. Admit that USP 797 requires an ISO 5 space for stoppering vials of MPA.

ANSWER:

45. Admit that NECC stoppered the Contaminated Lots in an ISO 7 space.

ANSWER:

46. Admit that the documents attached as Exhibit E are true and accurate copies of emails you sent to Glenn Chin in the normal course of NECC's business.

ANSWER:

47. Admit that in the email you sent Glenn Chin on Wednesday, August 10, attached as Exhibit E, you stated, "I am told that the lots for some drugs almost never coincide with the available test data."

ANSWER:

48. Admit that in the email you sent Glenn Chin on Wednesday, August 10, attached as Exhibit E, you stated, "I was told that we are only testing rarely and dispensing many untested lots."

ANSWER:

49. Admit that Exhibit F is a true and accurate copy of an email you received from Glenn Chin on Monday, December 19, 2011.

ANSWER:

50. Admit that the email in Exhibit F was sent in the normal course of NECC's business.

ANSWER:

51. Admit that in the email attached as Exhibit F, Glenn Chin indicated that he was using "MTX" that had expired in 2007 in NECC's injectable products in 2011.

ANSWER:

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio
C.J. Gideon, Jr.*
Chris J. Tardio*
Alan S. Bean**
Matthew H. Cline*
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Attorneys for the Tennessee Clinic Defendants

* Admitted pursuant to MDL Order No. 1.
** Admitted *pro hac vice*.

CERTIFICATE OF SERVICE

I hereby certify that on the 31st day of March, 2015, a true and accurate copy of the foregoing was served on Barry Cadden by U.S. mail and on the other parties below electronically via the Court's CM/ECF system:

Gerard Stranch, IV Ben Gastel Branstetter, Stranch & Jennings, PLLC 227 2nd Ave N Suite 400 Nashville, TN 37201 *Attorneys for the PSC* [via hand-delivery, to upload to repository]	Matthew P. Moriarty Thomas W. Coffey Richard A. Dean Tucker Ellis, LLP 950 Main Avenue, Suite 1100 Cleveland, OH 44113 Scott H. Kremer Tucker, Heifetz & Saltzman Three School Street Boston, MA 02108 Scott J. Tucker Paul Saltzman Matthew E. Mantalos Tucker, Saltzman & Dyer, LLP 50 Congress Street Boston, MA 02109 *Attorneys for Defendant Ameridose, LLC*
Daniel M. Rabinovitz Brady J. Hermann Nicki Samson Michaels, Ward & Rabinovitz One Beacon Street , 2nd Floor Boston, MA 02108 *Attorneys for Defendant Medical Sales Management, Inc.*	John P. Ryan Robert H. Gaynor William J. Dailey, Jr. Sloane and Walsh, LLP Three Center Plaza Boston, MA 02108 *Attorneys for Gregory Conigliaro, Registered Agent for Service of Process for Medical Sales Management SW, Inc.*

Joseph P. Thomas Ulmer & Berne, LLP 600 Vine Street, Suite 2800 Cincinnati, OH 45202 Joshua A. Klarfeld Ulmer & Berne, LLP 1660 W.2nd Street, Suite 1100 Cleveland, OH 44113 *Attorneys for Defendant* *GDC Properties Management, LLC*	Kenneth B. Walton Kristen R. Ragosta Donovan Hatem, LLP Two Seaport Lane, 8th Floor Boston, MA 02210 *Attorneys for Defendant* *ARL Bio Pharma*
John P. Ryan Robert H. Gaynor William J. Dailey, Jr. Sloane and Walsh, LLP Three Center Plaza Boston, MA 02108 *Attorneys for Defendants Barry J. Cadden, Lisa Conigliaro Cadden, Gregory Conigliaro, Carla Conigliaro, Douglas Conigliaro and Glenn A. Chin* Bruce A. Singal Michelle R. Peirce Callan G. Stein Donague, Barrett & Singal, P.C. One Beacon Street , Suite 1320 Boston, MA 02108 *Attorneys for Defendants Barry J. Cadden and Lisa Conigliaro Cadden*	Damian W. Wilmot James Rehnquist Abigail K. Hemani Roberto M. Braceras Goodwin Procter LLP Exchange Place 53 State Street Boston, MA 02109 *Attorneys for Unifirst Corporation a/d/b/a Uniclean Cleanroom Services* Parks Chastain Jason Lee Brewer, Krause, Brooks, Chastain & Burrow, PLLC 611 Commerce St., Suite 2600 P.O. Box 23890 Nashville, TN 37202 615-256-8787 Fax: 615-256-8985 *Attorneys for Specialty Surgery Center, Crossville, PLLC*

Frederick H. Fern Judi Abbott Curry Jessica Saunders Eichel Alan M. Winchester Harris Beach PLLC 100 Wall Street 23rd Floor New York, NY 10005 Geoffrey M. Coan Daniel E. Tranen Hinshaw & Culbertson LLP 28 State Street 24th Floor Boston, MA 02109 Michael R. Gottfried Thomas B.K. Ringe, III Jennifer Mikels Duane Morris LLP 100 High Street Suite 2400 Boston, MA 02110-1724 *Attorneys for NECC*	Marcy H. Greer Alexander Dubose Jefferson & Townsent 515 Congress Ave. Suite 2350 Austin, TX 78701 Yvonne K. Puig Eric Hoffman Fulbright & Jaworski L.L.P. 98 San Jacinto Blvd. Suite 1100 Austin, TX 78701 Sarah P. Kelly Nutter, McClennen & Fish, LLP Seaport West 155 Seaport Boulevard Boston, MA 02210-2604 *Attorneys for the Saint Thomas Entities*

/s/ Chris J. Tardio
Chris J. Tardio

EXHIBIT B

Logged Formula Worksheet (standard)
5/21/2012 9:58:08 AM
Page 1

LG229933

NEW ENGLAND COMPOUNI
697 WAVERLY ST.
697 WAVERLY ST.
FRAMINGHAM, MA 01702 Ph

N — 17.125 g-7
N — 82.375 g-6
N — 28.500 g-3
N — 352.500 g-2

Log ID: 22993

METHYLPRED. AC (PF) 80MG/ML INJECTABLE

Flavor:
Description:
Schedule: L

Quantity made: 12500 ML
Batch yield: 12,500.000
Qty remaining: 12,500.000
PCCA ID:
Route of admin:

Date made: 5/21/2012
Lot number: 05212012@68
Beyond use date: November 17, 2012 9:57 AM
180 days after compounding date
Pharmacist: GC
Technician: JOSEPH P CONNOLLY
NDC1:
Packaging:
Equipment:

Pricing calculations fr	
Estimated price	$9.
Ingredient cost	$0.
Device cost	$0.
Time cost	$0.
Profit	

05-11-12 A09:05 OUT

Labeling: SHAKE WELL***SDV***
Stability information:

	Chemicals	Sch.	Quantity used	QS		
1	METHYLPREDNISOLONE ACETATE USP (STERILE) PI Lot #: ~~78740/A~~ Chemical Code: Balance: 8113/A	- Mfg: Volume: Medisca Potency:	1000 GM Exp. date: ~~4/30/2016~~ QS amount: NDC: 49452-4688-02	☑		04-30-12 A09:48 OUT
2	POLYETHYLENE GLYCOL 3350 NF (STERILE) BASE Lot #: 77089/A Chemical Code: Balance:	- Mfg: MEDISCA Volume: Potency:	352.5 GM Exp. date: 2/28/2014 QS amount: NDC:	☐	$7,755.00 Whlsr: MEDISCA AWP: Each ML contains 0.0282 GM or 2.82%	07/21/2005 $0.00 ChemInvID: 0
3	SODIUM CHLORIDE (STERILE) GRANULE Lot #: 11020203 Chemical Code: Balance:	- Mfg: MEDISCA Volume: Potency:	28.5 GM Exp. date: 11/10/2013 QS amount: NDC: 51927108700	☐	$0.56 Whlsr: MEDISCA AWP: Each ML contains 0.00228 GM or 0.228%	04/02/2012 $5.13 ChemInvID: 0
	WATER FOR INJECTION INJ Lot #: J2B670 Chemical Code: Balance:	Mfg: BRAUN Volume: Potency:	12500 ML Exp. date: 8/31/2014 QS amount: NDC: 00409488799	☒	$25,000.00 Whlsr: BRAUN AWP: Each ML contains 1 ML or 100%	06/17/2005 $61.13 ChemInvID: 300
5	POLYSORBATE 80 (STERILE) LIQUID Lot #: 79814/C Chemical Code: Balance:	O Mfg: MEDISCA Volume: Potency:	47.5 ML Exp. date: 8/31/2013 QS amount: NDC:	☐	$0.00 Whlsr: MEDISCA AWP: Each ML contains 0.0038 ML or 0.38%	04/02/2009 $0.00 ChemInvID: 170
6	SODIUM PHOSPHATE MONOBASIC (STERILE) POWDI Lot #: 11010925 Chemical Code: Balance:	- Mfg: LETCO Volume: Potency:	82.375 GM Exp. date: 8/11/2013 QS amount: NDC:	☐	$82.38 Whlsr: PROFESSIONAL COMPOUN AWP: Each ML contains 0.00659 GM or 0.659%	09/30/2008 $0.00 ChemInvID: 0
7	SODIUM PHOSPHATE DIBASIC (STERILE) POWDER Lot #: ~~C140892~~ Chemical Code: Balance: K32403	Mfg: PCCA Volume: JT Baker Potency:	17.125 GM Exp. date: 8/1/2012 QS amount: NDC:	☐	$0.00 Whlsr: PROFESSIONAL COMPOUN AWP: Each ML contains 0.00137 GM or 0.137%	11/01/2011 $0.00 ChemInvID: 289
			(Added all GM & GMS: 1,480.50)		$32,837.94	

Log Instructions & Notes

Originally made as: 12500 METHYLPRED. AC (PF) 80MG/ML INJECTABLE
Calculated lot number: 05212012@68 Beyond use date: 11/17/2012
FORMULA INSTRUCTIONS:

ZEBRA BAR CODES:
99600010504 - 1mL VIAL
99600020504 - 2mL VIAL
99600050504 - 5mL VIAL

Date entered: 5/21/2012 9:57:45 AM **Last modified:** 5/21/2012 9:58:06 AM **by:** LAB
Checked by: _____ **Date:** _____

MODEL No. MLS-3381

OPERATION DATE 2012/05/21
TIME PM 08:45:12

COURSE 1

CYCLE STARTED

TIME ELAPSED	TEMP CENT.	PRESS kPa	STATUS CYCLE
00:11:56	090.0	14	HEAT
00:13:59	100.0	24	HEAT
00:22:01	108.4	30	HEAT
00:25:25	121.0	104	STERI.
00:27:25	121.8	110	STERI.
00:29:25	121.8	111	STERI.
00:31:25	121.6	109	STERI.
00:33:25	121.7	111	STERI.
00:35:25	121.7	111	STERI.
00:37:25	121.6	110	STERI.
00:39:25	121.7	112	STERI.
00:40:29	121.7	112	COOL
01:14:15	064.9	5	COMPLETE

START TIME PM 08:45:12
END TIME PM 09:59:27

Logged Formula Worksheet (standard)
6/29/2012 9:06:36 AM
Page 1

LG235896

NEW ENGLAND COMPOUNI
697 WAVERLY ST.
697 WAVERLY ST.
FRAMINGHAM, MA 01702 PI

M + 352.504 g
M + 28.506 g
M + 82.376 g
M + 17.123 g

METHYLPRED. AC (PF) 80MG/ML INJECTABLE

Flavor:
Description:
Schedule: L
Formula ID: 2228
Log ID: 235896

BF Approved 06-29-2012

Quantity made: 12500 ML
Batch yield: 12,500.000
Qty remaining: 12,500.000
PCCA ID:
Route of admin:

Date made: 6/29/2012
Lot number: 06292012@26
Beyond use date: December 26, 2012 9:06 AM
180 days after compounding date
Pharmacist: GC
Technician: <NONE>
NDC1:
Packaging:
Equipment:

Pricing calculations from t	
Estimated price	$9.00 as
Ingredient cost	$0.00
Device cost	$0.00
Time cost	$
Profit	$

15L

SB

06-27-12 A11:41 OUT

Labeling: SHAKE WELL***SDV***
Stability information:

teflon

05-24-12 P03:42 OUT

Chemicals	*Sch.*	*Quantity used*	*QS*	*(B*
1 METHYLPREDNISOLONE ACETATE USP (STERILE) P(Lot #: ~~78740/A~~ Mfg: Medisca Chemical Code: Volume: Potency: Balance: 32872/B	-	2x500gm = 1000 GM Exp. date: ~~4/30/2016~~ 01-30-17 QS amount: NDC: 49452-4688-02	☐	Whls
2 POLYETHYLENE GLYCOL 3350 NF (STERILE) BASE Lot #: 77089/A Mfg: MEDISCA Chemical Code: Volume: Potency: Balance:	-	352.5 GM Exp. date: 2/28/2014 QS amount: NDC:	☐	Whlsr: MEDISCA $7,755.00 07/21/2005 AWP: $0.60 Each ML contains 0.0282 GM or 2.82% ChemInvID: 0
3 SODIUM CHLORIDE (STERILE) GRANUALE Lot #: 11020203 Mfg: MEDISCA Chemical Code: Volume: Potency: Balance:	-	28.5 GM Exp. date: 11/10/2013 QS amount: NDC: 51927108700	☐	Whlsr: MEDISCA $0.56 04/02/2012 AWP: $0.13 Each ML contains 0.00228 GM or 0.228% ChemInvID: 0
WATER FOR INJECTION INJ Lot #: J2A488 Mfg: BRAUN Chemical Code: Volume: Potency: Balance:		12500 ML Exp. date: 7/31/2014 QS amount: NDC: 00409488799	☒	Whlsr: BRAUN $25,000.00 06/17/2005 AWP: $61.13 Each ML contains 1 ML or 100% ChemInvID: 300
5 POLYSORBATE 80 (STERILE) LIQUID Lot #: 79814/C Mfg: MEDISCA Chemical Code: Volume: Potency: Balance:	O	47.5 ML Exp. date: 8/31/2013 QS amount: NDC:	☐	Whlsr: MEDISCA $0.00 04/02/2009 AWP: $0.00 Each ML contains 0.0038 ML or 0.38% ChemInvID: 170
6 SODIUM PHOSPHATE MONOBASIC (STERILE) POWDI Lot #: 11010925 Mfg: LETCO Chemical Code: Volume: Potency: Balance:	-	82.375 GM Exp. date: 8/11/2013 QS amount: NDC:	☐	Whlsr: PROFESSIONAL COMPOUN $82.38 09/30/2008 AWP: $0.08 Each ML contains 0.00659 GM or 0.659% ChemInvID: 0
7 SODIUM PHOSPHATE DIBASIC (STERILE) POWDER Lot #: ~~C140892~~ K32473 Mfg: ~~PCCA~~ J.T. BAKER Chemical Code: Volume: Potency: Balance:		17.125 GM Exp. date: ~~8/1/2013~~ 5-31-2013 QS amount: NDC:	☐	Whlsr: PROFESSIONAL COMPOUN $0.00 11/01/2011 AWP: $0.00 Each ML contains 0.00137 GM or 0.137% ChemInvID: 289
(Added all GM & GMS: 1,480.50)				$32,837.94

Hosp. ...

Log Instructions & Notes

Originally made as: 12500 METHYLPRED. AC (PF) 80MG/ML INJECTABLE
Calculated lot number: 06292012@26 Beyond use date: 12/26/2012
FORMULA INSTRUCTIONS:

ZEBRA BAR CODES:
99600010504 - 1mL VIAL
99600020504 - 2mL VIAL
99600050504 - 5mL VIAL

1L Walgreens
Lot # - 1070553
Exp - Apr '17

pH=5.0 (paper) 575 (?) KT=60'

Date entered: 6/29/2012 9:06:22 AM Last modified: 6/29/2012 9:06:34 AM by: LAB
Checked by: CBH Date: 06/12/12

cc BASE Beaker

necc

06-22-12 P03:05 OUT

BASE S_0 B_0

MODEL No. NLS-3781

OPERATION DATE 2012/06/30
TIME PM 08:01:18

COURSE 1

CYCLE STARTED

TIME ELAPSED	TEMP CENT.	PRESS kPa	STATUS CYCLE
00:09:53	090.0	6	HEAT
00:13:28	100.0	23	HEAT
00:21:30	101.5	10	HEAT
00:25:41	121.0	104	STERI.
00:27:41	121.8	110	STERI.
00:29:41	121.8	110	STERI.
00:31:41	121.8	110	STERI.
00:33:41	121.6	110	STERI.
00:35:41	121.8	112	STERI.
00:37:41	121.7	112	STERI.
00:39:41	121.6	111	STERI.
00:40:46	121.6	114	COOL
01:15:00	064.9	4	COMPLETE

START TIME PM 08:01:18
END TIME PM 09:16:18

Logged Formula Worksheet (standard)
6/29/2012 9:06:36 AM
Page 2

LG235896

NEW ENGLAND COMPOUNDING CTR
697 WAVERLY ST.
697 WAVERLY ST.
FRAMINGHAM, MA 01702 Ph. 800-994-6322

METHYLPRED. AC (PF) 80MG/ML INJECTABLE

Flavor:
Description:

Schedule: L

Active ☑
Formula ID: 2228
Log ID: 235896

Quantity made: 12500 ML

Batch yield: 12,500.000
Qty remaining: 12,500.000

PCCA ID:
Route of admin:

12/09/09 POLYSORBATE-80 DOUBLED FROM 0.194ML/100ML TO 0.38ML/100ML GC

MATERIALS: STERILE BEAKER, STERILE SPIN BAR, STERILE HOMOGENIZER ELEMENT
medisca 500gm plastic bottle weighs 98gms, plastic seal ring weighs 0.7gms
medisca 1kg plastic bottle weighs 145gms, WITH TOP
1) WEIGH CHEMICALS IN STERILE WEIGH CUPS ON ELECTRONIC ANALYTICAL BALANCE
2) IN HOOD DISSOLVE BASE-B, SODIUM PHOSPHATE MONOBASIC, SODIUM PHOSPHATE DIBASIC, SODIUM CHLORIDE, AND POLYSORBATE -80 IN VORTEX OF 80% FINAL VOLUME OF STERILE WATER.FILTER SOLUTION THROUGH A 0.22MICRON NALGENE FILTER.
3) SLOWLY ADD METHYLPREDNISOLONE ACETATE TO VORTEX OF ABOVE SOLUTION.
4) HOMOGENIZE AT HIGH SPEED FOR 2-5 MINUTES (VOLUME DEP.)
5) QS TO FINAL VOLUME WITH STERILE WATER FOR INJECTION.
6) COVER WITH MULTIPLE LAYERS OF FOIL AND SEAL WITH AUTOCLAVE INDICATOR TAPE
7) AUTOCLAVE AT 121C-15PSI-20MIN
####SPRAY EXTERIOR OF SEALED BEAKER WITH 70% IPA#####
8) RETURN TO HOOD AND REHOMOGENIZE. CREATE VORTEX AND ALLOW TO SOIN TILL COOLED TO ROOM TEMP.
9) FILL STERILE AMBER VIALS USING BAXA REPEATER PUMP VIA DISPOSABLE STERILE TUBING
10) CAP ,CRIMP, AND LABEL

####PULL RANDOM VIALS FOR APPROPRIATE ANALYSIS#####

Date entered: 6/29/2012 9:06:22 AM Last modified: 6/29/2012 9:06:34 AM by: LAB
Checked by: _____ Date: ____/____/_____

Logged Formula Worksheet (standard)
8/10/2012 2:43:06 PM
Page 1

LG242264

NEW ENGLAND COMPOUN
697 WAVERLY ST.
697 WAVERLY ST.
FRAMINGHAM, MA 01702

N + 352.506 g
N + 28.501 g
N + 82.377 g
N + 17.129 g

METHYLPRED. AC (PF) 80MG/ML INJECTABLE

Flavor:
Description:

Schedule: L

Active ☑
Formula ID: 2228
BF 08-10-2012

Quantity made: 12500 ML
Batch yield: 12,500.000
Qty remaining: 12,500.000
PCCA ID:
Route of admin:

Date made: 8/10/2012
Lot number: 08102012@51
Beyond use date: February 6, 2013 2:42 PM
180 days after compounding date
Pharmacist: GC
Technician: JOSEPH P CONNOLLY
NDC1:
Packaging:
Equipment:

Pricing calculations from the l	
Estimated price	$9.00 as of
Ingredient cost	$0.00
Device cost	$0
Time cost	$0
Profit	$9

08-07-12 A11:12 OUT

Labeling: SHAKE WELL***SDV***
Stability information:

Chemicals	*Sch.*	*Quantity used*	*QS*	*(Balance)*
1 METHYLPREDNISOLONE ACETATE USP (STERILE) P(- 2 x 500 gm = ; Lot #: ~~78740/A~~; Chemical Code:; Balance: 81113/G + 80494/B; Mfg: Mediscg; Volume:; Potency:		1000 GM; Exp. date: ~~4/30/2016~~ 09-30-16 + 09-30-16; QS amount:; NDC: 49452-4688-02	☐	Whlsr:; Each
POLYETHYLENE GLYCOL 3350 NF (STERILE) BASE; Lot #: 76985/A; Chemical Code:; Balance:; Mfg: MEDISCA; Volume:; Potency:	-	352.5 GM; Exp. date: 8/31/2013; QS amount:; NDC:	☐	Whlsr:; Each N; ChemInvID: 0
SODIUM CHLORIDE (STERILE) GRANUALE; Lot #: 11020203; Chemical Code:; Balance:; Mfg: MEDISCA; Volume:; Potency:	-	28.5 GM; Exp. date: 11/10/2013; QS amount:; NDC: 51927108700	☐	Whlsr: MEDISCA; $0.56 4/2/2012; AWP: $5.13; Each ML contains 0.00228 GM or 0.228%; ChemInvID: 0
WATER FOR INJECTION INJ; Lot #: J2B670; Chemical Code:; Balance:; Mfg: BRAUN; Volume:; Potency:		12500 ML; Exp. date: 8/31/2014; QS amount:; NDC: 00409488799	☒	Whlsr: BRAUN; $25,000.00 6/17/2005; AWP: $61.13; Each ML contains 1 ML or 100%; ChemInvID: 300
5 POLYSORBATE 80 (STERILE) LIQUID; Lot #: 79814/C; Chemical Code:; Balance:; Mfg: MEDISCA; Volume:; Potency:	O	47.5 ML; Exp. date: 8/31/2013; QS amount:; NDC:	☐	Whlsr: MEDISCA; $0.00 4/2/2009; AWP: $0.00; Each ML contains 0.0038 ML or 0.38%; ChemInvID: 170
SODIUM PHOSPHATE MONOBASIC (STERILE) POWDI; Lot #: 11010925; Chemical Code:; Balance:; Mfg: LETCO; Volume:; Potency:	-	82.375 GM; Exp. date: 8/11/2013; QS amount:; NDC:	☐	Whlsr: PROFESSIONAL COMPOUN; $82.38 9/30/2008; AWP: $0.00; Each ML contains 0.00659 GM or 0.659%; ChemInvID: 0
SODIUM PHOSPHATE DIBASIC (STERILE) POWDER; Lot #: ~~G140892~~; Chemical Code:; Balance: K39H09; Mfg: ~~PCCA~~ J.T. BAKER; Volume:; Potency:		17.125 GM; Exp. date: ~~8/1/2013~~; QS amount: 08-31-2013; NDC:	☐	Whlsr: PROFESSIONAL COMPOUN; $0.00 11/1/2011; AWP: $0.00; Each ML contains 0.00137 GM or 0.137%; ChemInvID: 289

(Added all GM & GMS: 1,480.50) $32,837.94

06-29-12 A11:24 OUT

Log Instructions & Notes

Originally made as: 12500 METHYLPRED. AC (PF) 80MG/ML INJECTABLE
Calculated lot number: 08102012@51 Beyond use date: 2/6/2013
FORMULA INSTRUCTIONS:

ZEBRA BAR CODES:
99600010504 - 1mL VIAL
99600020504 - 2mL VIAL
99600050504 - 5mL VIAL

pH= 5.4 (paper) 72° 5ye (?)

IL Valyeres
1071243-Lot#
Exp - APR'17

Date entered: 8/10/2012 2:42:54 PM Last modified: 8/10/2012 2:43:04 PM by: LAB
Checked by: [signature] Date: 08/10/2012

EXHIBIT C

New England Compounding Center
General Overview of
Policies & Procedures for Compounding Sterile Products

A. Facility/Equipment

a. Class 10,000 clean room – positive pressure with anteroom for scrubbing & gowning

b. Class 100 laminar flow hood

c. Certified by Massachusetts Board of Pharmacy (Tel: 617.727.9953) as a pharmacy with a central venous admixture service (CIVAS) in accordance with Board Regulations

B. Monitoring & Maintenance

a. Hood validated on yearly basis by Scientific Air Analysis, Inc. of Ashland, MA. Tel: 508-881-7100

b. Prefilters changed on monthly basis

c. Clean room area is cleaned on a weekly basis – floor/walls/fixtures

A. Sodium hypochlorite 0.5%

B. 70% isopropyl alcohol

C. Tightly woven non-shedding wipes

d. Compounding area is cleaned (all surfaces) using 70% isopropyl alcohol and non-shedding wipes before and after all compounding procedures using proper technique.

E. Use by Dating

Each vial is labeled with a use-by date appropriate to the formulation.

F. Packaging

Compounded preparations are packaged in containers meeting USP standards. Container used depends on the physical and chemical properties of the compounded preparation.

G. Dispensing

Product is dispensed by prescription only. There must be a specific practitioner-patient-pharmacist relationship to dispense to an individual patient or a facility.

H. Shipping

Medications are shipped overnight (usually FedEx) in a appropriate container to ensure controlled temperatures and product integrity.

Revised Nov 2002

EXHIBIT D

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: New England Compounding Center-MA

ARL #: 176896-01
LOT #: 05212012@68
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 05/22/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Methylprednisolone Acetate Specifications = 90% - 110%	80	mg/mL	83.604	104.5%	HPLC	5/23/2012

alex tang - Laboratory Supervisor

05/24/2012
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center-MA

ARL #: 176896-01
LOT #: 05212012@68
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 05/22/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	Sterile	USP 71	05/22/2012
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	05/23/2012

Amar Arafat - Microbiologist — 06/05/2012 Date Reported

Sterility - 14 day sterility report. In accordance with the USP guidelines, the samples will be incubated for 14 days.

Results reported above relate only to the sample that was tested.

ARL Form QUF-078-V4 03/05/2010

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center-MA

ARL #: 176896-01
LOT #: 05212012@68
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 05/22/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	Sterile	USP 71	05/22/2012
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	05/23/2012

Sterility - This preliminary report was issued after approximately 72 hours of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal - This preliminary report was issued after 4-5 days of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: EL = K/M where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg
Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)
Radiopharmaceutical parenteral: K is 175/V or Intrathecal radiopharmaceuticals: K is 14/V, where V is the maximum recommended dose in mL.
Dermal Application: K/M, where K = 5 EU/kg and M is the (maximum dose/m2/hour × 1.80 m2)/70 Kg.

Amar Arafat - Microbiologist

05/25/2012
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: New England Compounding Center-MA

ARL #: 180509-01
LOT #: 06292012@26
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 07/03/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Methylprednisolone Acetate Specifications = 90% - 110%	80	mg/mL	81.451	101.8%	HPLC	7/5/2012

Alex Tang - Laboratory Supervisor

07/05/2012
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center-MA

ARL #: 180509-01
LOT #: 06292012@26
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 07/03/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	Sterile	USP 71	07/03/2012
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	07/06/2012

Sample properties cause turbidity in growth media. Per USP 71; the sample will be inoculated into new growth media after 14 days of incubation and incubated for 4 additional days.

Amar Arafat - Microbiologist

07/17/2012
Date Reported

Sterility - 14 day sterility report. In accordance with the USP guidelines, the samples will be incubated for 14 days.

Results reported above relate only to the sample that was tested.

ARL Form QUF-078-V4 03/05/2010

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center-MA

ARL #: 180509-01
LOT #: 06292012@26
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 07/03/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	Sterile	USP 71	07/03/2012
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	07/06/2012

Sterility - This preliminary report was issued after approximately 72 hours of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal - This preliminary report was issued after 4-5 days of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: EL = K/M where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg
Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)
Radiopharmaceutical parenteral: K is 175/V or Intrathecal radiopharmaceuticals: K is 14/V, where V is the maximum recommended dose in mL.
Dermal Application: K/M, where K = 5 EU/kg and M is the (maximum dose/m2/hour × 1.80 m2)/70 Kg.

Amar Arafat - Microbiologist

07/06/2012
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: New England Compounding Center
697 Waverly Street
Framingham, MA 01702

ARL #: 184460-01
LOT #: 08102012@51
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 08/14/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Methylprednisolone Acetate Specifications = 90% - 110%	80	mg/mL	81.676	102.1%	HPLC	8/15/2012

Alex Tang - Laboratory Supervisor

08/15/2012
Date

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: New England Compounding Center
697 Waverly Street
Framingham, MA 01702

ARL #: 184460-01
LOT #: 08102012@51
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 08/14/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Methylprednisolone Acetate Specifications = 90% - 110%	80	mg/mL	81.676	102.1%	HPLC	8/15/2012

08/15/2012

Alex Tang - Laboratory Supervisor — Date

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center

ARL #: 184460-01
LOT #: 08102012@51
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 08/14/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	08/16/2012

Sample properties cause turbidity in growth media. Per USP 71, the sample will be inoculated into new growth media after 14 days of incubation and incubated for 4 additional days.

Tiffany O. Hyde

Tiffany Hyde - Microbiologist

08/17/2012
Date Reported

Sterility – This preliminary report was issued after approximately 72 hours of incubation. In accordance with the USP guidelines, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal – This preliminary report was issued after approximately 4 days of incubation. In accordance with the USP guidelines, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: EL = K/M where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg
Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)
Radiopharmaceutical parenteral: K is 175/V or Intrathecal radiopharmaceuticals: K is 14/V, where V is the maximum recommended dose in mL.
Dermal Application: K/M, where K = 5 EU/kg and M is the (maximum dose/m2/hour × 1.80 m2)/70 Kg.

Results reported above relate only to the sample that was tested.

ARL Form QUF-078-V5 08/20/2012

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center
697 Waverly Street
Framingham, MA 01702

ARL #: 184460-01
LOT #: 08102012@51
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 08/14/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	No Growth at 14 Days	USP 71	08/14/2012

Sample properties cause turbidity in growth media. Per USP 71, the sample will be inoculated into new growth media after 14 days of incubation and incubated for 4 additional days.

Tiffany O. Hyde

Tiffany Hyde - Microbiologist

08/28/2012
Date Reported

Sterility – 14 day sterility report. In accordance with the USP guidelines, the sample was incubated for 14 days.

Fungal – 14 day fungal report. In accordance with the USP guidelines, the sample was incubated for 14 days.

Results reported above relate only to the sample that was tested.

ARL Form QUF-078-V5 08/20/2012

EXHIBIT E

From: Barry Cadden </O=FIRST ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BCADDEN>
Sent: Wednesday, August 10, 2011 10:37 AM
To: Glenn Chin <gchin@neccrx.com>
Subject:

What's the testing process for the large volume meds currently? I assumed that we have at least sterility testing for "all" lots of large volume injectable lots that we are dispensing but I am told that the lots for some drugs almost never coincide with the available test data. Is this true? You need to run like normal stock meds like beta repos = test every lot and just fill as you go based on the size vial + # needed or make as many lots as you like "internally" but only label vials with lot# of tested lots to cover our ass =ex.. Avastin. I was told that we are only testing rarely and dispensing many untested lots? Please clear this up + tell me what we are doing + will do. Botton line is we can't be caught with our pants at our ankles....ever.

From: Barry Cadden </O=FIRST ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BCADDEN>
Sent: Tuesday, May 22, 2012 1:50 PM
To: Glenn Chin <gchin@neccrx.com>
Subject:

This situation is exactly why Scott must be swapped into a less dangerous position! We would be fucked if this was a cardio med!!!.....

From: Barry Cadden </O=FIRST ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BCADDEN>
Sent: Tuesday, August 7, 2012 9:16 AM
To: Glenn Chin <gchin@neccrx.com>
Subject:

The "problem" CP order has my name as sign in for pump!....we need to get Scott out of that room or at least off the sign in by tomorrow. Have him be there , help, train...etc but someone else MUST sign in .....I have no idea how I am going to explain this situation but it can't continue beyong today.....see me later

thanks

From: Barry Cadden
Sent: Tuesday, July 03, 2012 2:20 PM
To: Glenn Chin
Subject:

What's going on with the materials (mops..etc) for the Uniclean, cleaning people? How are they being handled?...I ask because we have another fungal bloom on June-28th=day of last cleaning. Are the pharmacists watching these idiots or sleeping? We need to keep an eye on them + make sure that the mops..etc are not contaminated. I am getting the film again so we can check it out.....

EXHIBIT F

From: Glenn Chin </O=FIRST ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=GCHIN>
Sent: Monday, December 19, 2011 11:36 AM
To: Barry Cadden <bcadden@neccrx.com>; Cory Fletcher <cfletcher@neccrx.com>
Subject: RE: MTX

We have about 1.25KG of MTX left. It's the old Spectrum bottles. When I say old I mean OLD, it expired in 2007 according to their sticker. We make it for our injectables and we send it out for testing and it comes out pretty close. We generally under QS the lot's we make. I would probably guess that it's at about 90 to 95% potent.

From: Barry Cadden
Sent: Monday, December 19, 2011 9:32 AM
To: Glenn Chin; Gene Svirskiy; Cory Fletcher
Subject: MTX

How much MTX powder to we have in house? I am hearing that there is another backorder of commercial inj. MTX + can't find a chemical co. who has any powder in stock

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	MDL No. 2419
	)	Dkt. No. 1:13-md-2419-RWZ
This Document Relates to Suits Naming:	)	
Suits Naming the Tennessee Clinic Defendants	)	

THE TENNESSEE CLINIC DEFENDANTS' FIRST INTERROGATORIES, REQUESTS FOR PRODUCTON OF DOCUMENTS, AND REQUESTS FOR ADMISSION PROPOUNDED TO GLENN CHIN.

Come the Defendants, Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants") , pursuant to Rules 26, 33, and 34 of the Federal Rules of Civil Procedure and the Local Rules for the District of Massachusetts, and propound the following Interrogatories, Requests for Production of Documents, and Requests for Admission to Glenn Chin.

Each of the following Interrogatories shall be answered under oath, in writing, separately, to the fullest possible detail, and in accordance with the definitions and instructions set forth below. The answers shall be signed by the person making them, and a copy of the answers, together with objections, if any, shall be served within thirty (30) days after the service date of these Interrogatories.

You are under a duty to seasonably supplement your response with respect to any Interrogatory directly addressed to the identity and location of persons having knowledge of discoverable matters. You are under a duty to amend a prior response if you obtain information on the basis of which you know that the response was incorrect when made, or that the response, though correctly made, is no longer true, and the circumstances are such that a failure to amend the response is, in substance, a knowing concealment.

DEFINITIONS

1. As used in this document, the terms "person(s)" and "individual(s)" mean any natural individual in any capacity whatsoever or any entity or organization, including divisions, departments, and other units therein, and shall include, but not be limited to, a public or private corporation, partnership, joint venture, voluntary or unincorporated association, organization, proprietorship, trust, estate, governmental agency, commission, bureau, or department.

2. As used in this document, the term "document" means any medium upon which intelligence or information can be recorded or retrieved, and includes without limitation, the original and each copy, regardless of origin and location, of any book, pamphlet, periodical, letter, memorandum (including any memorandum or report of a meeting or conversation), invoice, bill, order form, receipt, financial statement, accounting entry, diary, calendar, telex, telegram, cable, report, record, contract, agreement, study, handwritten note, draft, working paper, chart, paper, print, laboratory record, drawing or sketch, graph, index, lists, tape, photograph, microfilm, data sheet or data processing card, or any other written, recorded, transcribed, punched, taped, filmed, or graphic matter, however produced or reproduced, which is in your possession, custody, or control, or which was, but is no longer, in your possession, custody, or control.

3. As used in this document, the terms "identification," "identify," or "identity," when used in reference to a natural individual, require you to state his or her full name and residential and business address. Use of the term "document" in connection with the Interrogatories requires you to state the number of pages and the nature of the document, its title, its date, the name or names of its authors, and recipients, and its present location and custodian.

4. "You" and "your" refers to Glenn Chin and each of his present and former agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on his behalf.

5. "Communication" means any oral or written utterance, notification, or statement of any nature whatsoever, by and to whomsoever made, including, but not limited to, correspondence, conversation, dialogue, discussions, interviews, consultants, and any other understanding between or among two or more persons.

INSTRUCTIONS

1. With respect to each Interrogatory, in addition to answering the question, you are to identify all documents that support, refer to, or evidence the subject matter of each Interrogatory and your answer thereto.

   If any or all identified documents are no longer in your possession, custody, or control because of destruction, loss, or any other reason, then you must do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and the copy of the document;

   D. State in as much detail as possible the contents of the documents; and

   E. State the manner and date of disposition of the document.

   If you contend that you are entitled to withhold from production any or all documents identified herein on the basis of attorney-client privilege, the work-product doctrine, or any other ground, then do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and a copy of the document;

   D. State the subject matter of the document; and

   E. State the basis upon which you contend you are entitled to withhold the document from production.

2. All documents produced should be organized and labeled to correspond to the specific Request in response to which they are being made available or should be produced as they are kept in the usual course of business.

3. The terms "and," "or," and "and/or" should be construed either disjunctively or conjunctively so as to bring within the scope of these Interrogatories and Requests any information that might otherwise be construed as outside their scope.

4. The term "any" should be construed to include the word "all," and "all" should be construed to include "any."

5. The present tense should be construed to include the past tense, and the past tense should be construed to include the present tense.

6. The singular should be construed to include the plural, and the plural should be construed to include the singular.

7. The terms "he" and "his" should be construed to include the words "she" and "her" or "hers," respectively and vice versa.

8. "Relating to," when referring to a document shall mean mentioning, describing, connected to or with, or discussing the stated subject matter.

INTERROGATORIES

On March 19, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to Glenn Chin.* In order to minimize the impact of discovery on Glenn Chin, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Interrogatories 1-6** from the *Saint Thomas Entities' First Set of Interrogatories.* The "new" interrogatories begin at Number 7.

1-6. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Interrogatories 1-11 from the *Saint Thomas Entities' First Set of Interrogatories.*]

ANSWER:

7. Describe in detail your role at NECC and Ameridose, including job title, job description, and a description of your daily duties and activities in 2011 and 2012.

ANSWER:

8. Describe in detail the steps NECC took to compound, process, stopper, seal, package, and ship methylprednisolone acetate ("MPA") in 2011 and 2012, including but not limited to:

   a. The names of the individuals performing each step;

   b. The job titles for the individuals performing each step;

   c. The specific cleanroom or location in NECC's facility where each step took place;

   d. The tools, equipment, or machinery used for each step;

   e. Any changes to NECC's methods or procedures for compounding MPA, or the location where compounding MPA took place, that occurred in 2011 or 2012.

ANSWER:

9. Identify the total amount of MPA that NECC, and separately Ameridose, produced in each quarter of 2010, 2011, and 2012.

ANSWER:

10. Identify the types of vials and closures NECC used for MPA lots numbered 052122012@68, 06292012@26, and 08102012@51 (collectively "Contaminated Lots"), including whether the vials and enclosures were prewashed or

presterilized, and identify their manufacturer(s) and from whom they were purchased by NECC.

ANSWER:

11. Identify any and all complaints that NECC and Ameridose received related to the sterility or safety of their products, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER:

12. Identify any customers of NECC and Ameridose who performed site visits prior to placing orders with either company.

ANSWER:

13. Describe any policies, procedures, or protocols relating to or regarding customer site visits to the NECC facility, including the areas you allowed customers to inspect.

ANSWER:

14. Identify any customers who took the following actions prior to placing orders with NECC or Ameridose:

    a. Verified whether NECC's quality processes demonstrated that NECC was a reputable and safe supplier of sterile injectable compounds;

    b. Determined if NECC was an accredited compounding pharmacy;

    c. At least once annually, unannounced, visited NECC's corporate offices and compounding facilities and conferred with NECC's corporate, pharmacy, and compounding staff;

    d. Determined whether NECC had any product liability lawsuits filed against it for preparations compounded;

    e. Determined whether there had ever been recalls of any of NECC's compounded preparations;

    f. Evaluated NECC's standard operating procedures and manuals;

    g. Evaluated NECC's pharmacist technician training;

    h. Evaluated NECC's policies and procedures for sterility testing;

i. Evaluated examples of batch reports for product being considered for outsourcing;

j. Evaluated examples of quality-control reports;

k. Obtained and evaluated history of the results of all NECC accreditation or regulatory surveys conducted of NECC's sites, including copies of significant regulatory actions;

l. Determined if NECC could provide documentation of the end-product testing processes used to determine that compounded sterile preparations are sterile and free of pyrogens and unintended particulate matter;

m. Evaluated whether NECC could assure that each compounded sterile preparation was sterile and free of pyrogens and unintended particulate matter according to professional established and accepted quality monitoring data;

n. Determined whether NECC performed nonviable and viable particle testing in primary engineering controls (e.g., laminar flow workbench, biological safety cabinet) and room air according to USP chapter 797 standards;

o. Determined whether NECC performed routine surface microbiological and fungal environmental monitoring to minimize contamination;

p. Determined whether NECC had a policy that required validation of new or changed facilities, equipment, processes, or container types, for sterility and repeatability;

q. Determined whether NECC met ASHP, NIOSH and USP chapter 797 guidelines for the handling of hazardous agents;

r. Evaluated NECC's quality management program, specifically as it relates to facility cleaning and validation, staff training, and competency assessment;

s. Evaluated NECC's risk assessment program to ensure that medication errors are not introduced by new or increased outsourced compounding activities; or

t. Determined whether NECC had a history of disciplinary or punitive actions by any regulatory agency.

ANSWER:

15. Describe any information you, NECC, or Ameridose provided to each customer in response to the inquiries identified in the previous Interrogatory.

ANSWER:

16. Identify any and all complaints NECC or Ameridose received related to their compliance with state or federal laws and regulations, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER:

17. Identify and describe any way in which NECC's cleanrooms were modified, altered, or expanded by NECC or Ameridose.

ANSWER:

18. Identify any policies, procedures, or guidelines in place at NECC in 2012 that encouraged employees to disclose mistakes in the compounding process, even if the mistakes necessitated destruction of product or halting production.

ANSWER:

19. Describe all disciplinary or enforcement action taken against NECC or Ameridose by any state or federal government agency.

ANSWER:

20. Describe in detail Lisa Conigliaro Cadden's role at NECC in 2011 and 2012.

ANSWER:

VERIFICATION

STATE OF TENNESSEE)
)
COUNTY OF _____)

I, _____, after being duly sworn, hereby make oath that the foregoing answers to interrogatories are true to the best of my knowledge, information, and belief.

_____

Sworn to and subscribed before me this _____ day of _____, 2015.

_____
Notary Public

My commission expires on: _____.

REQUESTS FOR PRODUCTION

On March 19, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to Glenn Chin.* In order to minimize the impact of discovery on Glenn Chin, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Requests for Production 1-39** from the *Saint Thomas Entities' First Requests for Production.* The "new" requests begin at Number 40.

1-39. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Requests for Production 1-39 from the *Saint Thomas Entities' First Requests for Production.*]

RESPONSE:

40. Produce all correspondence between you and any of the Tennessee Clinic Defendants, their employees, agents, or representatives.

RESPONSE:

41. Produce all correspondence and documents referring or relating to the Tennessee Clinic Defendants' purchase of MPA from NECC in 2011 or 2012.

RESPONSE:

42. Produce all documents produced by the government to you during any civil, criminal, or administrative proceedings related to NECC's contaminated MPA.

RESPONSE:

43. Produce all policies, procedures, guidelines, instructions and training documents referring or relating to the compounding of MPA at the NECC facility.

RESPONSE:

44. Produce all documents referring or relating to NECC or Ameridose sending sufficient samples, by size or volume, to comply with USP 71 to ARL or any other testing laboratory.

RESPONSE:

45. Produce all documents referring or relating to any sterility, potency, endotoxin, or fungal testing that you received from ARL or any other laboratory related to MPA compounded by NECC or Ameridose in 2011 and 2012.

RESPONSE:

46. Produce all correspondence and documents referring or relating to fungal blooms or growth in or near NECC's cleanrooms.

RESPONSE:

47. Produce all documents referring or relating to any complaints that NECC or Ameridose received related to the sterility or safety of their products, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

48. Produce all documents referring or relating to any complaints NECC or Ameridose received related to their compliance with state or federal laws and regulations, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

49. Produce all correspondence and documents referring or relating to NECC's response to the meningitis outbreak, including but not limited to, steps NECC took to prepare for any inspections of its facility.

RESPONSE:

50. Produce all training and instructional material for sales staff at NECC or MSM.

RESPONSE:

REQUESTS FOR ADMISSION

On March 19, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to Glenn Chin.* In order to minimize the impact of discovery on Glenn Chin, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Requests for Admission 1-17** from the *Saint Thomas Entities' First Requests for Admission.* The "new" requests begin at Number 18.

1-17. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Requests for Admission 1-17 from the *Saint Thomas Entities' First Requests for Admission*.]

ANSWER:

18. Admit that you compounded the MPA lots numbered 052122012@68, 06292012@26, and 08102012@51 (collectively "Contaminated Lots").

ANSWER:

19. Admit that you supervised the compounding of MPA lots numbered 052122012@68, 06292012@26, and 08102012@51 (collectively "Contaminated Lots").

ANSWER:

20. Admit that as a supervising pharmacist, you owed a duty to the Plaintiffs to ensure that NECC's cleanroom was sterile prior to compounding any medications, including MPA in 2012.

ANSWER:

21. Admit that as a supervising pharmacist, you owed a duty to the Plaintiffs to ensure that the MPA you compounded was sterile before you distributed it to customers.

ANSWER:

21. Admit that, had any of the Tennessee Clinic Defendants asked for a copy of NECC's license in 2011, you would have provided a valid and up-to-date Massachusetts pharmacy license.

ANSWER:

22. Admit that NECC represented to its customers, including the Tennessee Clinic Defendants, that it met or exceeded USP 797 standards.

ANSWER:

23. Admit that NECC represented to its customers, including the Tennessee Clinic Defendants, that its products, including MPA, were safe and sterile.

ANSWER:

24. Admit that the Massachusetts Board of Pharmacy ("Mass. BoP") inspected NECC on or about May 24, 2011.

ANSWER:

25. Admit that as a result of its inspection on or about May 24, 2011 the Mass. BoP issued an inspection report documenting its findings.

ANSWER:

26. Admit that NECC failed to submit a copy of the Mass. BoP's May 24, 2011 inspection report to the Tennessee Board of Pharmacy.

ANSWER:

27. Admit that the documents attached as Exhibit B are NECC's Logged Formula Worksheets for the Contaminated Lots.

ANSWER:

28. Admit that in each Logged Formula Worksheet in Exhibit B, the pharmacist referred to as "GC" is Glenn Chin.

ANSWER:

29. Admit that the Logged Formula Worksheet for lot 06292012@26, attached as Exhibit B, states that the MPA was autoclaved for twenty (20) minutes at 121 C. and 15 PSI.

ANSWER:

30. Admit that NECC's Standard Operating Procedures required that the MPA be autoclaved for fifteen (15) minutes at 121 C. and 15 PSI.

ANSWER:

31. Admit that the Logged Formula Worksheets in Exhibit B state that Joseph P. Connolly was the technician for MPA lots 052122012@68 and 06292012@26.

ANSWER:

32. Admit that Exhibit C is NECC's General Overview of Policies & Procedures for Compounding Sterile Products.

ANSWER:

33. Admit that Exhibit C states, in part:

C. Personnel
a. All sterile compounding is performed by properly trained and validated pharmacists (*no* technicians).

ANSWER:

34. Admit that NECC violated its own standard operating procedures by permitting Joseph Connolly (a technician) to compound two of the three contaminated lots.

ANSWER

35. Admit that you owed a duty to NECC's customers to ensure that NECC's MPA was sterile prior to distributing it.

ANSWER:

36. Admit that NECC distributed some of the MPA from the Contaminated Lots prior to receiving final sterility, fungal, endotoxin, or potency testing results from its outside laboratory.

ANSWER:

37. Admit that the documents attached as Exhibit D are reports from Analytical Research Laboratories ("ARL") related to the sterility and endotoxin testing ARL performed on NECC's MPA from the Contaminated Lots.

ANSWER:

38. Admit that NECC submitted only two 5 mL vials of MPA from each of the Contaminated Lots to ARL for testing.

ANSWER:

39. Admit that USP standards for sterility testing required a larger sample size than two 5 mL vials per lot of MPA.

ANSWER:

40. Admit that USP 797 requires an ISO 5 space for stoppering vials of MPA.

ANSWER:

41. Admit that NECC stoppered the Contaminated Lots in an ISO 7 space.

ANSWER:

42. Admit that the documents attached as Exhibit E are true and accurate copies of emails you received from Barry Cadden in the normal course of NECC's business.

ANSWER:

43. Admit that in the email you received from Barry Cadden on Wednesday, August 10, attached as Exhibit E, Barry Cadden stated, "I am told that the lots for some drugs almost never coincide with the available test data."

ANSWER:

44. Admit that in the email you received from Barry Cadden on Wednesday, August 10, attached as Exhibit E, Barry Cadden stated, "I was told that we are only testing rarely and dispensing many untested lots."

ANSWER:

45. Admit that Exhibit F is a true and accurate copy of an email you sent to Barry Cadden on Monday, December 19, 2011.

ANSWER:

46. Admit that the email in Exhibit F was sent in the normal course of NECC's business.

ANSWER:

47. Admit that in the email attached as Exhibit F, you indicated that you were using "MTX" that had expired in 2007 in NECC's injectable products in 2011.

ANSWER:

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio
C.J. Gideon, Jr.*
Chris J. Tardio*
Alan S. Bean**
Matthew H. Cline*
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Nashville, TN 37238
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chris@gideoncooper.com

Attorneys for the Tennessee Clinic Defendants

* Admitted pursuant to MDL Order No. 1.
** Admitted *pro hac vice*.

CERTIFICATE OF SERVICE

I hereby certify that on the 31st day of March, 2015, a true and accurate copy of the foregoing was served on Glenn Chin by U.S. mail and on the other parties below electronically via the Court's CM/ECF system:

Gerard Stranch, IV Ben Gastel Branstetter, Stranch & Jennings, PLLC 227 2nd Ave N Suite 400 Nashville, TN 37201 *Attorneys for the PSC* [via hand-delivery, to upload to repository]	Matthew P. Moriarty Thomas W. Coffey Richard A. Dean Tucker Ellis, LLP 950 Main Avenue, Suite 1100 Cleveland, OH 44113 Scott H. Kremer Tucker, Heifetz & Saltzman Three School Street Boston, MA 02108 Scott J. Tucker Paul Saltzman Matthew E. Mantalos Tucker, Saltzman & Dyer, LLP 50 Congress Street Boston, MA 02109 *Attorneys for Defendant Ameridose, LLC*
Daniel M. Rabinovitz Brady J. Hermann Nicki Samson Michaels, Ward & Rabinovitz One Beacon Street , 2nd Floor Boston, MA 02108 *Attorneys for Defendant Medical Sales Management, Inc.*	John P. Ryan Robert H. Gaynor William J. Dailey, Jr. Sloane and Walsh, LLP Three Center Plaza Boston, MA 02108 *Attorneys for Gregory Conigliaro, Registered Agent for Service of Process for Medical Sales Management SW, Inc.*

Joseph P. Thomas Ulmer & Berne, LLP 600 Vine Street, Suite 2800 Cincinnati, OH 45202 Joshua A. Klarfeld Ulmer & Berne, LLP 1660 W.2nd Street, Suite 1100 Cleveland, OH 44113 *Attorneys for Defendant* *GDC Properties Management, LLC*	Kenneth B. Walton Kristen R. Ragosta Donovan Hatem, LLP Two Seaport Lane, 8th Floor Boston, MA 02210 *Attorneys for Defendant* *ARL Bio Pharma*
John P. Ryan Robert H. Gaynor William J. Dailey, Jr. Sloane and Walsh, LLP Three Center Plaza Boston, MA 02108 *Attorneys for Defendants Barry J. Cadden, Lisa Conigliaro Cadden, Gregory Conigliaro, Carla Conigliaro, Douglas Conigliaro and Glenn A. Chin* Bruce A. Singal Michelle R. Peirce Callan G. Stein Donague, Barrett & Singal, P.C. One Beacon Street , Suite 1320 Boston, MA 02108 *Attorneys for Defendants Barry J. Cadden and Lisa Conigliaro Cadden*	Damian W. Wilmot James Rehnquist Abigail K. Hemani Roberto M. Braceras Goodwin Procter LLP Exchange Place 53 State Street Boston, MA 02109 *Attorneys for Unifirst Corporation a/d/b/a Uniclean Cleanroom Services* Parks Chastain Jason Lee Brewer, Krause, Brooks, Chastain & Burrow, PLLC 611 Commerce St., Suite 2600 P.O. Box 23890 Nashville, TN 37202 615-256-8787 Fax: 615-256-8985 *Attorneys for Specialty Surgery Center, Crossville, PLLC*

Frederick H. Fern Judi Abbott Curry Jessica Saunders Eichel Alan M. Winchester Harris Beach PLLC 100 Wall Street 23rd Floor New York, NY 10005 Geoffrey M. Coan Daniel E. Tranen Hinshaw & Culbertson LLP 28 State Street 24th Floor Boston, MA 02109 Michael R. Gottfried Thomas B.K. Ringe, III Jennifer Mikels Duane Morris LLP 100 High Street Suite 2400 Boston, MA 02110-1724 *Attorneys for NECC*	Marcy H. Greer Alexander Dubose Jefferson & Townsent 515 Congress Ave. Suite 2350 Austin, TX 78701 Yvonne K. Puig Eric Hoffman Fulbright & Jaworski L.L.P. 98 San Jacinto Blvd. Suite 1100 Austin, TX 78701 Sarah P. Kelly Nutter, McClennen & Fish, LLP Seaport West 155 Seaport Boulevard Boston, MA 02210-2604 *Attorneys for the Saint Thomas Entities*

/s/ Chris J. Tardio
Chris J. Tardio

EXHIBIT B

Logged Formula Worksheet (standard)
5/21/2012 9:58:08 AM
Page 1

LG229933

NEW ENGLAND COMPOUNI
697 WAVERLY ST.
697 WAVERLY ST.
FRAMINGHAM, MA 01702 Ph

N — 17.125 g-7
N — 82.378 g-6
N — 28.593 g-3
N — 352.501 g-2

METHYLPRED. AC (PF) 80MG/ML INJECTABLE

Schedule: L

Flavor:
Description:
Quantity made: 12500 ML
Batch yield: 12,500.000
Qty remaining: 12,500.000

Log ID: 229933

PCCA ID:
Route of admin:

Pricing calculations fr	
Estimated price	$9.
Ingredient cost	$0.
Device cost	$0.
Time cost	$0.
Profit	

Date made: 5/21/2012
Lot number: 05212012@68
Beyond use date: November 17, 2012 9:57 AM
180 days after compounding date
Pharmacist: GC
Technician: JOSEPH P CONNOLLY
NDC1:
Packaging:
Equipment:

15<
SB

05-11-12 A09:05 OUT

Labeling: SHAKE WELL***SDV***
Stability Information:

Chemicals | *Sch.* | *Quantity used* | *QS*

1 METHYLPREDNISOLONE ACETATE USP (STERILE) PI - | 1000 GM
Lot #: 78740/A | Mfg: | Exp. date: 4/30/2016
Chemical Code: | Volume: Medisca | Potency: | QS amount:
Balance: 8/1/13/A | NDC: 49452-4688-02
fellow
04-30-12 A09:48 OUT
Homo 05-02-12 ...

2 POLYETHYLENE GLYCOL 3350 NF (STERILE) BASE - | 352.5 GM | Whlsr: MEDISCA | $7,755.00 | 07/21/2005
Lot #: 77089/A | Mfg: MEDISCA | Exp. date: 2/28/2014 | AWP: $0.00
Chemical Code: | Volume: | Potency: | QS amount: | Each ML contains 0.0282 GM or 2.82%
Balance: | NDC: | CheminvID: 0

3 SODIUM CHLORIDE (STERILE) GRANUALE - | 28.5 GM | Whlsr: MEDISCA | $0.56 | 04/02/2012
Lot #: 11020203 | Mfg: MEDISCA | Exp. date: 11/10/2013 | AWP: $5.13
Chemical Code: | Volume: | Potency: | QS amount: | Each ML contains 0.00228 GM or 0.228%
Balance: | NDC: 51927108700 | CheminvID: 0

4 WATER FOR INJECTION INJ | 12500 ML | Whlsr: BRAUN | $25,000.00 | 06/17/2005
Lot #: J2B670 | Mfg: BRAUN | Exp. date: 8/31/2014 | AWP: $61.13
Chemical Code: | Volume: | Potency: | QS amount: | Each ML contains 1 ML or 100%
Balance: | NDC: 00409488799 | CheminvID: 300

5 POLYSORBATE 80 (STERILE) LIQUID O | 47.5 ML | Whlsr: MEDISCA | $0.00 | 04/02/2009
Lot #: 79814/C | Mfg: MEDISCA | Exp. date: 8/31/2013 | AWP: $0.00
Chemical Code: | Volume: | Potency: | QS amount: | Each ML contains 0.0038 ML or 0.38%
Balance: | NDC: | CheminvID: 170

6 SODIUM PHOSPHATE MONOBASIC (STERILE) POWDI - | 82.375 GM | Whlsr: PROFESSIONAL COMPOUN | $82.38 | 09/30/2008
Lot #: 11010925 | Mfg: LETCO | Exp. date: 8/11/2013 | AWP: $0.00
Chemical Code: | Volume: | Potency: | QS amount: | Each ML contains 0.00659 GM or 0.659%
Balance: | NDC: | CheminvID: 0

7 SODIUM PHOSPHATE DIBASIC (STERILE) POWDER | 17.125 GM | Whlsr: PROFESSIONAL COMPOUN | $0.00 | 11/01/2011
Lot #: ~~C140892~~ | Mfg: ~~PCCA~~ | Exp. date: 8/4/2012 | AWP: $0.00
Chemical Code: | Volume: JT Baker | Potency: | QS amount: | Each ML contains 0.00137 GM or 0.137%
Balance: K32473 | NDC: | CheminvID: 289

(Added all GM & GMS: 1,480.50) $32,837.94

Log Instructions & Notes

Originally made as: 12500 METHYLPRED. AC (PF) 80MG/ML INJECTABLE
Calculated lot number: 05212012@68 Beyond use date: 11/17/2012
FORMULA INSTRUCTIONS: 12 Nalgene filters
HT=60' Sy(Y) ph=5.0 / paper

ZEBRA BAR CODES:
99600010504 - 1mL VIAL
99600020504 - 2mL VIAL
99600050504 - 5mL VIAL

Lot K 106193
exp: 01-17

Date entered: 5/21/2012 9:57:45 AM
Last modified: 5/21/2012 9:58:06 AM by: LAB
Checked by: G Date: 05/16/12

MODEL No. MLS-[illegible]81

OPERATION DATE 2012/05/21
TIME PM 08:45:12

COURSE 1

CYCLE STARTED

TIME ELAPSED	TEMP CENT.	PRESS kPa	STATUS CYCLE
00:11:56	090.0	14	HEAT
00:13:59	100.0	24	HEAT
00:22:01	106.4	30	HEAT
00:25:25	121.0	104	STERI.
00:27:25	121.8	110	STERI.
00:29:25	121.8	111	STERI.
00:31:25	121.6	109	STERI.
00:33:25	121.7	111	STERI.
00:35:25	121.7	111	STERI.
00:37:25	121.6	110	STERI.
00:39:25	121.7	112	STERI.
00:40:29	121.7	112	COOL
01:14:15	064.9	5	COMPLETE

START TIME PM 08:45:12
END TIME PM 09:59:27

Logged Formula Worksheet (standard)

6/29/2012 9:06:36 AM
Page 1

LG235896

NEW ENGLAND COMPOUND
697 WAVERLY ST.
697 WAVERLY ST.
FRAMINGHAM, MA 01702 P

N + 352.594 g
N + 28.506 g
N + 82.376 g
N + 17.123 g

Formula ID: 2228
Log ID: 235896

METHYLPRED. AC (PF) 80MG/ML INJECTABLE

Schedule: L

Flavor:
Description:
Quantity made: 12500 ML

Batch yield: 12,500.000
Qty remaining: 12,500.000

PCCA ID:
Route of admin:

Pricing calculations from t
Estimated price $9.00 as
Ingredient cost $0.00
Device cost $0.00
Time cost $
Profit $

Date made: 6/29/2012
Lot number: 06292012@26
Beyond use date: December 26, 2012 9:06 AM
180 days after compounding date
Pharmacist: GC
Technician: <NONE>
NDC1:
Packaging:
Equipment:

06-27-12 A11:41 OUT

Labeling: SHAKE WELL***SDV***
Stability information:

	Chemicals	Sch.	Quantity used	QS (B	
1	METHYLPREDNISOLONE ACETATE USP (STERILE) PI - 2x500gm = 1000 GM Lot #: ~~78749/A~~ Mfg: Chemical Code: Volume: Potency: Balance: 32872B Medisca		Exp. date: ~~4/30/2016~~ 01-30-17 QS amount: NDC: 49452-4688-02	☐	Whls
2	POLYETHYLENE GLYCOL 3350 NF (STERILE) BASE - Lot #: 77089/A Mfg: MEDISCA Chemical Code: Volume: Potency: Balance:		352.5 GM Exp. date: 2/28/2014 QS amount: NDC:	☐	$7,755.00 07/21/2005 Whlsr: MEDISCA AWP: $0.00 Each ML contains 0.0282 GM or 2.82% ChemInvID: 0
3	SODIUM CHLORIDE (STERILE) GRANUALE - Lot #: 11020203 Mfg: MEDISCA Chemical Code: Volume: Potency: Balance:		28.5 GM Exp. date: 11/10/2013 QS amount: NDC: 51927108700	☐	$0.56 04/02/2012 Whlsr: MEDISCA AWP: $5.13 Each ML contains 0.00228 GM or 0.228% ChemInvID: 0
4	WATER FOR INJECTION INJ Lot #: J2A488 Mfg: BRAUN Chemical Code: Volume: Potency: Balance:		12500 ML Exp. date: 7/31/2014 QS amount: NDC: 00409488799	☒	$25,000.00 06/17/2005 Whlsr: BRAUN AWP: $61.13 Each ML contains 1 ML or 100% ChemInvID: 300
5	POLYSORBATE 80 (STERILE) LIQUID O Lot #: 79814/C Mfg: MEDISCA Chemical Code: Volume: Potency: Balance:		47.5 ML Exp. date: 8/31/2013 QS amount: NDC:	☐	$0.00 04/02/2009 Whlsr: MEDISCA AWP: $0.00 Each ML contains 0.0038 ML or 0.38% ChemInvID: 170
6	SODIUM PHOSPHATE MONOBASIC (STERILE) POWDI - Lot #: 11010925 Mfg: LETCO Chemical Code: Volume: Potency: Balance:		82.375 GM Exp. date: 8/11/2013 QS amount: NDC:	☐	$82.38 09/30/2008 Whlsr: PROFESSIONAL COMPOUN AWP: $0.00 Each ML contains 0.00659 GM or 0.659% ChemInvID: 0
7	SODIUM PHOSPHATE DIBASIC (STERILE) POWDER Lot #: ~~C140892~~ Mfg: PCCA Chemical Code: Volume: J.T. Potency: Balance: K32473 BAKER		17.125 GM Exp. date: ~~8/1/2013~~ QS amount: 05-31-2013 NDC:	☐	$0.00 11/01/2011 Whlsr: PROFESSIONAL COMPOUN AWP: $0.00 Each ML contains 0.00137 GM or 0.137% ChemInvID: 289
			(Added all GM & GMS: 1,480.50)		$32,837.94

Log Instructions & Notes

Originally made as: 12500 METHYLPRED. AC (PF) 80MG/ML INJECTABLE
Calculated lot number: 06292012@26 Beyond use date: 12/26/2012
FORMULA INSTRUCTIONS:

ZEBRA BAR CODES:
99600010504 - 1mL VIAL
99600020504 - 2mL VIAL
99600050504 - 5mL VIAL

Date entered: 6/29/2012 9:06:22 AM Last modified: 6/29/2012 9:06:34 AM by: LAB
Checked by: Date:

cc BASE Beaker

NECC

06-22-12 P03:05 OUT

BASE S_0 B_0

MODEL No. MLS-3781

OPERATION DATE 2012/06/30
TIME PM 08:01:18

COURSE 1

CYCLE STARTED

TIME ELAPSED	TEMP CENT.	PRESS kPa	STATUS CYCLE
00:09:53	090.0	6	HEAT
00:13:28	100.0	23	HEAT
00:21:30	101.5	10	HEAT
00:25:41	121.0	104	STERI.
00:27:41	121.8	110	STERI.
00:29:41	121.8	110	STERI.
00:31:41	121.8	110	STERI.
00:33:41	121.6	110	STERI.
00:35:41	121.8	112	STERI.
00:37:41	121.7	112	STERI.
00:39:41	121.6	111	STERI.
00:40:46	121.6	114	COOL
01:15:00	064.9	4	COMPLETE

START TIME PM 08:01:18
END TIME PM 09:16:18

Logged Formula Worksheet (standard)
6/29/2012 9:06:36 AM
Page 2

T.G235896

NEW ENGLAND COMPOUNDING CTR
697 WAVERLY ST.
697 WAVERLY ST.
FRAMINGHAM, MA 01702 Ph. 800-994-6322

METHYLPRED. AC (PF) 80MG/ML INJECTABLE

Flavor:
Description:
Schedule: L
Active ☑
Formula ID: 2228
Log ID: 235896

Quantity made: 12500 ML
Batch yield: 12,500.000
Qty remaining: 12,500.000
PCCA ID:
Route of admin:

12/09/09 POLYSORBATE-80 DOUBLED FROM 0.194ML/100ML TO 0.38ML/100ML GC

MATERIALS: STERILE BEAKER, STERILE SPIN BAR, STERILE HOMOGENIZER ELEMENT
medisca 500gm plastic bottle weighs 98gms, plastic seal ring weighs 0.7gms
medisca 1kg plastic bottle weighs 145gms, WITH TOP
1) WEIGH CHEMICALS IN STERILE WEIGH CUPS ON ELECTRONIC ANALYTICAL BALANCE
2) IN HOOD DISSOLVE BASE-B, SODIUM PHOSPHATE MONOBASIC, SODIUM PHOSPHATE DIBASIC, SODIUM CHLORIDE, AND POLYSORBATE -80 IN VORTEX OF 80% FINAL VOLUME OF STERILE WATER.FILTER SOLUTION THROUGH A 0.22MICRON NALGENE FILTER.
3) SLOWLY ADD METHYLPREDNISOLONE ACETATE TO VORTEX OF ABOVE SOLUTION.
4) HOMOGENIZE AT HIGH SPEED FOR 2-5 MINUTES (VOLUME DEP.)
5) QS TO FINAL VOLUME WITH STERILE WATER FOR INJECTION.
6) COVER WITH MULTIPLE LAYERS OF FOIL AND SEAL WITH AUTOCLAVE INDICATOR TAPE
7) AUTOCLAVE AT 121C-15PSI-20MIN
####SPRAY EXTERIOR OF SEALED BEAKER WITH 70% IPA#####
8) RETURN TO HOOD AND REHOMOGENIZE. CREATE VORTEX AND ALLOW TO SOIN TILL COOLED TO ROOM TEMP.
9) FILL STERILE AMBER VIALS USING BAXA REPEATER PUMP VIA DISPOSABLE STERILE TUBING
10) CAP ,CRIMP, AND LABEL

####PULL RANDOM VIALS FOR APPROPRIATE ANALYSIS#####

Date entered: 6/29/2012 9:06:22 AM Last modified: 6/29/2012 9:06:34 AM by: LAB
Checked by: _____ Date: ___/___/_____

Logged Formula Worksheet (standard)
8/10/2012 2:43:06 PM
Page 1

LG242264

NEW ENGLAND COMPOUN
697 WAVERLY ST.
697 WAVERLY ST.
FRAMINGHAM, MA 01702

N + 352.506 g
N + 28.501 g
N + 82.377 g
N + 17.129 g

METHYLPRED. AC (PF) 80MG/ML INJECTABLE

Flavor:
Description:
Schedule: L
Active ☑
Formula ID: 2228
08-10-2012

Quantity made: 12500 ML
Batch yield: 12,500.000
Qty remaining: 12,500.000
PCCA ID:
Route of admin:

Date made: 8/10/2012
Lot number: 08102012@51
Beyond use date: February 6, 2013 — 2:42 PM
180 days after compounding date
Pharmacist: GC
Technician: JOSEPH P CONNOLLY
NDC1:
Packaging:
Equipment:

Pricing calculations from the l	
Estimated price	$9.00 as of
Ingredient cost	$0.00
Device cost	$0
Time cost	$0
Profit	$9

08-07-12 A11:12 OUT

Labeling: SHAKE WELL***SDV***
Stability information:

Chemicals	*Sch.*	*Quantity used*	*QS*	*(Balance)*
1 METHYLPREDNISOLONE ACETATE USP (STERILE) P(- 2 x 500 gm = ; Lot #: ~~78740/A~~; Mfg: Medisca; Chemical Code:; Volume:; Potency:; Balance: 81113/G + 80494/B		1000 GM; Exp. date: ~~4/30/2016~~ 09-30-16 + 09-30-16; QS amount:; NDC: 49452-4688-02	☐	Whlsr: ; Each
POLYETHYLENE GLYCOL 3350 NF (STERILE) BASE; Lot #: 76985/A; Mfg: MEDISCA; Chemical Code:; Volume:; Potency:; Balance:	-	352.5 GM; Exp. date: 8/31/2013; QS amount:; NDC:	☐	Whlsr: ; Each ML; ChemInvID: 0
SODIUM CHLORIDE (STERILE) GRANUALE; Lot #: 11020203; Mfg: MEDISCA; Chemical Code:; Volume:; Potency:; Balance:	-	28.5 GM; Exp. date: 11/10/2013; QS amount:; NDC: 51927108700	☐	$0.56 4/2/2012; Whlsr: MEDISCA; AWP: $5.13; Each ML contains 0.00228 GM or 0.228%; ChemInvID: 0
WATER FOR INJECTION INJ; Lot #: J2B670; Mfg: BRAUN; Chemical Code:; Volume:; Potency:; Balance:		12500 ML; Exp. date: 8/31/2014; QS amount:; NDC: 00409488799	☒	$25,000.00 6/17/2005; Whlsr: BRAUN; AWP: $61.13; Each ML contains 1 ML or 100%; ChemInvID: 300
5 POLYSORBATE 80 (STERILE) LIQUID; Lot #: 79814/C; Mfg: MEDISCA; Chemical Code:; Volume:; Potency:; Balance:	O	47.5 ML; Exp. date: 8/31/2013; QS amount:; NDC:	☐	$0.00 4/2/2009; Whlsr: MEDISCA; AWP: $0.00; Each ML contains 0.0038 ML or 0.38%; ChemInvID: 170
6 SODIUM PHOSPHATE MONOBASIC (STERILE) POWD; Lot #: 11010925; Mfg: LETCO; Chemical Code:; Volume:; Potency:; Balance:	-	82.375 GM; Exp. date: 8/11/2013; QS amount:; NDC:	☐	$82.38 9/30/2008; Whlsr: PROFESSIONAL COMPOUN; AWP: $0.00; Each ML contains 0.00659 GM or 0.659%; ChemInvID: 0
7 SODIUM PHOSPHATE DIBASIC (STERILE) POWDER; Lot #: ~~C140802~~ K391H09; Mfg: ~~PCCA~~ J.T. BAKER; Chemical Code:; Volume:; Potency:; Balance:		17.125 GM; Exp. date: ~~8/1/2013~~ 08-31-2013; QS amount:; NDC:	☐	$0.00 11/1/2011; Whlsr: PROFESSIONAL COMPOUN; AWP: $0.00; Each ML contains 0.00137 GM or 0.137%; ChemInvID: 289

06-29-12 A11:24 OUT

(Added all GM & GMS: 1,480.50) — $32,837.94

Log Instructions & Notes

Originally made as: 12500 METHYLPRED. AC (PF) 80MG/ML INJECTABLE
Calculated lot number: 08102012@51 Beyond use date: 2/6/2013
FORMULA INSTRUCTIONS:

ZEBRA BAR CODES:
99600010504 - 1mL VIAL
99600020504 - 2mL VIAL
99600050504 - 5mL VIAL

pH= 5.4 [illegible] 72' [illegible]

IL [illegible]
10 71243-Lot#
Exp - APR'17

Date entered: 8/10/2012 2:42:54 PM
Last modified: 8/10/2012 2:43:04 PM by: LAB
Checked by: [signature] Date: 08/10/2012

EXHIBIT C

New England Compounding Center
General Overview of
Policies & Procedures for Compounding Sterile Products

A. Facility/Equipment

a. Class 10,000 clean room – positive pressure with anteroom for scrubbing & gowning

b. Class 100 laminar flow hood

c. Certified by Massachusetts Board of Pharmacy (Tel: 617.727.9953) as a pharmacy with a central venous admixture service (CIVAS) in accordance with Board Regulations 21 (c) (5).

B. Monitoring & Maintenance

a. Hood validated on yearly basis by Scientific Air Analysis, Inc. of Ashland, MA. Tel: 508-881-7100

b. Prefilters changed on monthly basis

c. Clean room area is cleaned on a weekly basis – floor/walls/fixtures

A. Sodium hypochlorite 0.5%

B. 70% isopropyl alcohol

C. Tightly woven non-shedding wipes

d. Compounding area is cleaned (all surfaces) using 70% isopropyl alcohol and non-shedding wipes before and after all compounding procedures using proper technique.

E. Use by Dating

Each vial is labeled with a use-by date appropriate to the formulation.

F. Packaging

Compounded preparations are packaged in containers meeting USP standards. Container used depends on the physical and chemical properties of the compounded preparation.

G. Dispensing

Product is dispensed by prescription only. There must be a specific practitioner-patient-pharmacist relationship to dispense to an individual patient or a facility.

H. Shipping

Medications are shipped overnight (usually FedEx) in a appropriate container to ensure controlled temperatures and product integrity.

Revised Nov 2002

EXHIBIT D

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: New England Compounding Center-MA

ARL #: 176896-01
LOT #: 05212012@68
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 05/22/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Methylprednisolone Acetate Specifications = 90% - 110%	80	mg/mL	83.604	104.5%	HPLC	5/23/2012

alex tang - Laboratory Supervisor

05/24/2012
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center-MA

ARL #: 176896-01
LOT #: 05212012@68
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 05/22/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	Sterile	USP 71	05/22/2012
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	05/23/2012

Amar Arafat - Microbiologist

06/05/2012
Date Reported

Sterility - 14 day sterility report. In accordance with the USP guidelines, the samples will be incubated for 14 days.

Results reported above relate only to the sample that was tested.

ARL Form QUF-078-V4 03/05/2010

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center-MA

ARL #: 176896-01
LOT #: 05212012@68
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 05/22/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	Sterile	USP 71	05/22/2012
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	05/23/2012

Sterility - This preliminary report was issued after approximately 72 hours of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal - This preliminary report was issued after 4-5 days of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: EL = K/M where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg
Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)
Radiopharmaceutical parenteral: K is 175/V or Intrathecal radiopharmaceuticals: K is 14/V, where V is the maximum recommended dose in mL.
Dermal Application: K/M, where K = 5 EU/kg and M is the (maximum dose/m2/hour × 1.80 m2)/70 Kg.

Amar Arafat - Microbiologist

05/25/2012
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: New England Compounding Center-MA

ARL #: 180509-01
LOT #: 06292012@26
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 07/03/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Methylprednisolone Acetate Specifications = 90% - 110%	80	mg/mL	81.451	101.8%	HPLC	7/5/2012

Alex Tang - Laboratory Supervisor

07/05/2012
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center-MA

ARL #: 180509-01
LOT #: 06292012@26
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 07/03/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	Sterile	USP 71	07/03/2012
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	07/06/2012

Sample properties cause turbidity in growth media. Per USP 71; the sample will be inoculated into new growth media after 14 days of incubation and incubated for 4 additional days.

Amar Arafat

07/17/2012

Amar Arafat - Microbiologist — Date Reported

Sterility - 14 day sterility report. In accordance with the USP guidelines, the samples will be incubated for 14 days.

Results reported above relate only to the sample that was tested.

ARL Form QUF-078-V4 03/05/2010

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center-MA

ARL #: 180509-01
LOT #: 06292012@26
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 07/03/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	Sterile	USP 71	07/03/2012
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	07/06/2012

Sterility - This preliminary report was issued after approximately 72 hours of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal - This preliminary report was issued after 4-5 days of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: EL = K/M where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg
Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)
Radiopharmaceutical parenteral: K is 175/V or Intrathecal radiopharmaceuticals: K is 14/V, where V is the maximum recommended dose in mL.
Dermal Application: K/M, where K = 5 EU/kg and M is the (maximum dose/m2/hour × 1.80 m2)/70 Kg.

Amar Arafat - Microbiologist

07/06/2012
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: New England Compounding Center
697 Waverly Street
Framingham, MA 01702

ARL #: 184460-01
LOT #: 08102012@51
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 08/14/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Methylprednisolone Acetate Specifications = 90% - 110%	80	mg/mL	81.676	102.1%	HPLC	8/15/2012

Alex Tang - Laboratory Supervisor

08/15/2012
Date

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: New England Compounding Center
697 Waverly Street
Framingham, MA 01702

ARL #: 184460-01
LOT #: 08102012@51
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 08/14/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Methylprednisolone Acetate Specifications = 90% - 110%	80	mg/mL	81.676	102.1%	HPLC	8/15/2012

08/15/2012

Alex Tang - Laboratory Supervisor — Date

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center

ARL #: 184460-01
LOT #: 08102012@51
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 08/14/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	08/16/2012

Sample properties cause turbidity in growth media. Per USP 71, the sample will be inoculated into new growth media after 14 days of incubation and incubated for 4 additional days.

Tiffany O. Hyde

Tiffany Hyde - Microbiologist

08/17/2012
Date Reported

Sterility – This preliminary report was issued after approximately 72 hours of incubation. In accordance with the USP guidelines, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal – This preliminary report was issued after approximately 4 days of incubation. In accordance with the USP guidelines, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: EL = K/M where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg
Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)
Radiopharmaceutical parenteral: K is 175/V or Intrathecal radiopharmaceuticals: K is 14/V, where V is the maximum recommended dose in mL.
Dermal Application: K/M, where K = 5 EU/kg and M is the (maximum dose/m2/hour × 1.80 m2)/70 Kg.

Results reported above relate only to the sample that was tested.

ARL Form QUF-078-V5 08/20/2012

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center
697 Waverly Street
Framingham, MA 01702

ARL #: 184460-01
LOT #: 08102012@51
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 08/14/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	No Growth at 14 Days	USP 71	08/14/2012

Sample properties cause turbidity in growth media. Per USP 71, the sample will be inoculated into new growth media after 14 days of incubation and incubated for 4 additional days.

Tiffany O. Hyde

Tiffany Hyde - Microbiologist

08/28/2012
Date Reported

Sterility – 14 day sterility report. In accordance with the USP guidelines, the sample was incubated for 14 days.

Fungal – 14 day fungal report. In accordance with the USP guidelines, the sample was incubated for 14 days.

Results reported above relate only to the sample that was tested.

Page 1 of 1

ARL Form QUF-078-V5 08/20/2012

EXHIBIT E

From: Barry Cadden </O=FIRST ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BCADDEN>
Sent: Wednesday, August 10, 2011 10:37 AM
To: Glenn Chin <gchin@neccrx.com>
Subject:

What's the testing process for the large volume meds currently? I assumed that we have at least sterility testing for "all" lots of large volume injectable lots that we are dispensing but I am told that the lots for some drugs almost never coincide with the available test data. Is this true? You need to run like normal stock meds like beta repos = test every lot and just fill as you go based on the size vial + # needed or make as many lots as you like "internally" but only label vials with lot# of tested lots to cover our ass =ex.. Avastin. I was told that we are only testing rarely and dispensing many untested lots? Please clear this up + tell me what we are doing + will do. Botton line is we can't be caught with our pants at our ankles....ever.

From: Barry Cadden </O=FIRST ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BCADDEN>
Sent: Tuesday, May 22, 2012 1:50 PM
To: Glenn Chin <gchin@neccrx.com>
Subject:

This situation is exactly why Scott must be swapped into a less dangerous position! We would be fucked if this was a cardio med!!!.....

From: Barry Cadden </O=FIRST ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BCADDEN>
Sent: Tuesday, August 7, 2012 9:16 AM
To: Glenn Chin <gchin@neccrx.com>
Subject:

The "problem" CP order has my name as sign in for pump!....we need to get Scott out of that room or at least off the sign in by tomorrow. Have him be there , help, train...etc but someone else MUST sign in .....I have no idea how I am going to explain this situation but it can't continue beyong today.....see me later

thanks

From: Barry Cadden
Sent: Tuesday, July 03, 2012 2:20 PM
To: Glenn Chin
Subject:

What's going on with the materials (mops..etc) for the Uniclean, cleaning people? How are they being handled?...I ask because we have another fungal bloom on June-28th=day of last cleaning. Are the pharmacists watching these idiots or sleeping? We need to keep an eye on them + make sure that the mops..etc are not contaminated. I am getting the film again so we can check it out.....

EXHIBIT F

From: Glenn Chin </O=FIRST ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=GCHIN>
Sent: Monday, December 19, 2011 11:36 AM
To: Barry Cadden <bcadden@neccrx.com>; Cory Fletcher <cfletcher@neccrx.com>
Subject: RE: MTX

We have about 1.25KG of MTX left. It's the old Spectrum bottles. When I say old I mean OLD, it expired in 2007 according to their sticker. We make it for our injectables and we send it out for testing and it comes out pretty close. We generally under QS the lot's we make. I would probably guess that it's at about 90 to 95% potent.

From: Barry Cadden
Sent: Monday, December 19, 2011 9:32 AM
To: Glenn Chin; Gene Svirskiy; Cory Fletcher
Subject: MTX

How much MTX powder to we have in house? I am hearing that there is another backorder of commercial inj. MTX + can't find a chemical co. who has any powder in stock

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	MDL No. 2419
	)	Dkt. No. 1:13-md-2419-RWZ
This Document Relates to Suits Naming:	)	
Suits Naming the Tennessee Clinic Defendants	)	

THE TENNESSEE CLINIC DEFENDANTS' FIRST INTERROGATORIES, REQUESTS FOR PRODUCTON OF DOCUMENTS, AND REQUESTS FOR ADMISSION PROPOUNDED TO CARLA CONIGLIARO.

Come the Defendants, Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants") , pursuant to Rules 26, 33, and 34 of the Federal Rules of Civil Procedure and the Local Rules for the District of Massachusetts, and propound the following Interrogatories, Requests for Production of Documents, and Requests for Admission to Carla Conigliaro.

Each of the following Interrogatories shall be answered under oath, in writing, separately, to the fullest possible detail, and in accordance with the definitions and instructions set forth below. The answers shall be signed by the person making them, and a copy of the answers, together with objections, if any, shall be served within thirty (30) days after the service date of these Interrogatories.

You are under a duty to seasonably supplement your response with respect to any Interrogatory directly addressed to the identity and location of persons having knowledge of discoverable matters. You are under a duty to amend a prior response if you obtain information on the basis of which you know that the response was incorrect when made, or that the response, though correctly made, is no longer true, and the circumstances are such that a failure to amend the response is, in substance, a knowing concealment.

DEFINITIONS

1. As used in this document, the terms "person(s)" and "individual(s)" mean any natural individual in any capacity whatsoever or any entity or organization, including divisions, departments, and other units therein, and shall include, but not be limited to, a public or private corporation, partnership, joint venture, voluntary or unincorporated association, organization, proprietorship, trust, estate, governmental agency, commission, bureau, or department.

2. As used in this document, the term "document" means any medium upon which intelligence or information can be recorded or retrieved, and includes without limitation, the original and each copy, regardless of origin and location, of any book, pamphlet, periodical, letter, memorandum (including any memorandum or report of a meeting or conversation), invoice, bill, order form, receipt, financial statement, accounting entry, diary, calendar, telex, telegram, cable, report, record, contract, agreement, study, handwritten note, draft, working paper, chart, paper, print, laboratory record, drawing or sketch, graph, index, lists, tape, photograph, microfilm, data sheet or data processing card, or any other written, recorded, transcribed, punched, taped, filmed, or graphic matter, however produced or reproduced, which is in your possession, custody, or control, or which was, but is no longer, in your possession, custody, or control.

3. As used in this document, the terms "identification," "identify," or "identity," when used in reference to a natural individual, require you to state his or her full name and residential and business address. Use of the term "document" in connection with the Interrogatories requires you to state the number of pages and the nature of the document, its title, its date, the name or names of its authors, and recipients, and its present location and custodian.

4. "You" and "your" refers to Carla Conigliaro and each of his present and former agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on his behalf.

5. "Communication" means any oral or written utterance, notification, or statement of any nature whatsoever, by and to whomsoever made, including, but not limited to, correspondence, conversation, dialogue, discussions, interviews, consultants, and any other understanding between or among two or more persons.

INSTRUCTIONS

1. With respect to each Interrogatory, in addition to answering the question, you are to identify all documents that support, refer to, or evidence the subject matter of each Interrogatory and your answer thereto.

   If any or all identified documents are no longer in your possession, custody, or control because of destruction, loss, or any other reason, then you must do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and the copy of the document;

   D. State in as much detail as possible the contents of the documents; and

   E. State the manner and date of disposition of the document.

   If you contend that you are entitled to withhold from production any or all documents identified herein on the basis of attorney-client privilege, the work-product doctrine, or any other ground, then do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and a copy of the document;

   D. State the subject matter of the document; and

   E. State the basis upon which you contend you are entitled to withhold the document from production.

2. All documents produced should be organized and labeled to correspond to the specific Request in response to which they are being made available or should be produced as they are kept in the usual course of business.

3. The terms "and," "or," and "and/or" should be construed either disjunctively or conjunctively so as to bring within the scope of these Interrogatories and Requests any information that might otherwise be construed as outside their scope.

4. The term "any" should be construed to include the word "all," and "all" should be construed to include "any."

5. The present tense should be construed to include the past tense, and the past tense should be construed to include the present tense.

6. The singular should be construed to include the plural, and the plural should be construed to include the singular.

7. The terms "he" and "his" should be construed to include the words "she" and "her" or "hers," respectively and vice versa.

8. "Relating to," when referring to a document shall mean mentioning, describing, connected to or with, or discussing the stated subject matter.

INTERROGATORIES

On March 19, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to Carla Conigliaro.* In order to minimize the impact of discovery on Carla Conigliaro, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Interrogatories 1-6** from the *Saint Thomas Entities' First Set of Interrogatories.*

1-6. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Interrogatories 1-11 from the *Saint Thomas Entities' First Set of Interrogatories.*]

ANSWER:

7. Describe in detail your role at NECC and Ameridose, including job title, job description, and a description of your daily duties and activities in 2011 and 2012.

ANSWER:

8. Describe in detail the steps NECC took to compound, process, stopper, seal, package, and ship methylprednisolone acetate ("MPA") in 2011 and 2012, including but not limited to:

a) The names of the individuals performing each step;

b) The job titles for the individuals performing each step;

c) The specific cleanroom or location in NECC's facility where each step took place;

d) The tools, equipment, or machinery used for each step;

e) Any changes to NECC's methods and procedures for compounding MPA, or the location where compounding MPA took place, that occurred in 2011 or 2012.

ANSWER:

9. Identify the total amount of MPA that NECC, and separately Ameridose, produced in each quarter of 2010, 2011, and 2012.

ANSWER:

10. Identify the types of vials and closures NECC used for MPA lots numbered 052122012@68, 06292012@26, and 08102012@51 (collectively "Contaminated Lots"), including whether the vials and enclosures were prewashed or presterilized, and identify their manufacturer(s).

ANSWER:

11. Identify any and all complaints that NECC and Ameridose received related to the sterility or safety of their products, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER:

12. Identify any customers of NECC and Ameridose who performed site visits prior to placing orders with either company.

ANSWER:

13. Describe any policies, procedures, or protocols relating to or regarding customer site visits to the NECC facility, including the areas you allowed customers to inspect.

ANSWER:

14. Identify any customers who asked for information about prior recalls of NECC and Ameridose products prior to placing orders with either company.

ANSWER:

15. Identify and describe any information you gave customers about recalled NECC and Ameridose products in 2011 and 2012.

ANSWER:

16. Identify any and all complaints NECC or Ameridose received related to their compliance with state or federal laws and regulations, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER:

17. Identify and describe any way in which NECC's cleanrooms were modified, altered, or expanded by NECC or Ameridose.

ANSWER:

18. Identify any policies, procedures, or guidelines in place at NECC in 2012 that encouraged employees to disclose mistakes in the compounding process, even if the mistakes necessitated destruction of product or halting production.

ANSWER:

19. Describe all disciplinary or enforcement action taken against NECC or Ameridose by any state or federal government agency.

ANSWER:

20. Describe in detail Lisa Conigliaro Cadden's role at NECC in 2011 and 2012.

ANSWER:

VERIFICATION

STATE OF TENNESSEE)
)
COUNTY OF _____)

I, _____, after being duly sworn, hereby make oath that the foregoing answers to interrogatories are true to the best of my knowledge, information, and belief.

_____

Sworn to and subscribed before me this _____ day of _____, 2015.

_____
Notary Public

My commission expires on: _____.

REQUESTS FOR PRODUCTION

On March 19, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to Carla Conigliaro.* In order to minimize the impact of discovery on Carla Conigliaro, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Requests for Production 1-39** from the *Saint Thomas Entities' First Requests for Production.* The "new" requests begin at Number 40.

1-39. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Requests for Production 1-39 from the *Saint Thomas Entities' First Requests for Production.*]

RESPONSE:

40. Produce all correspondence between you and any of the Tennessee Clinic Defendants, their employees, agents, or representatives.

RESPONSE:

41. Produce all correspondence and documents referring or relating to the Tennessee Clinic Defendants' purchase of MPA from NECC in 2012.

RESPONSE:

42. Produce all documents produced by the government to you during any civil, criminal, or administrative proceedings related to NECC's contaminated MPA.

RESPONSE:

43. Produce all policies, procedures, guidelines, instructions and training documents referring or relating to the compounding of MPA at the NECC facility.

RESPONSE:

44. Produce all documents referring or relating to NECC or Ameridose sending samples of insufficient size or volume to comply with USP 71 to ARL or any other testing laboratory.

RESPONSE:

45. Produce all documents referring or relating to any sterility, potency, endotoxin, or fungal testing that you received from ARL or any other laboratory related to MPA compounded by NECC or Ameridose in 2011 and 2012.

RESPONSE:

46. Produce all correspondence and documents referring or relating to fungal blooms growth in or near NECC's cleanrooms.

RESPONSE:

47. Produce documents referring or relating to complaints or communications with Liberty regarding the design, manufacture, or installation of the clean rooms at the NECC facility.

RESPONSE:

48. Produce all documents referring or relating to any complaints that NECC or Ameridose received related to the sterility or safety of their products, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

49. Produce all documents referring or relating to any complaints NECC or Ameridose received related to their compliance with state or federal laws and regulations, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

50. Produce all correspondence and documents referring or relating to NECC's response to the meningitis outbreak, including but not limited to, steps NECC took to prepare for any inspections of its facility.

RESPONSE:

51. Produce all training and instructional material for sales staff at NECC or MSM.

RESPONSE:

REQUESTS FOR ADMISSION

On March 19, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to Carla Conigliaro.* In order to minimize the impact of discovery on Carla Conigliaro, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Requests for Admission 1-12** from the *Saint Thomas Entities' First Requests for Admission.* The "new" requests begin at Number 13.

1-12. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Requests for Admission 1-12 from the *Saint Thomas Entities' First Requests for Admission.*]

ANSWER:

13. Admit that, had any of the Tennessee Clinic Defendants asked for a copy of NECC's license in 2011, you would have provided a valid and up-to-date Tennessee pharmacy license.

ANSWER:

14. Admit that NECC represented to its customers, including the Tennessee Clinic Defendants, that it met or exceeded USP 797 standards.

ANSWER:

15. Admit that NECC represented to the Tennessee Clinic Defendants that its products, including MPA, were safe and sterile.

ANSWER:

16. Admit that the Massachusetts Board of Pharmacy ("Mass. BoP") inspected NECC on or about May 24, 2011.

ANSWER:

17. Admit that as a result of its inspection on or about May 24, 2011 the Mass. BoP issued an inspection report documenting its findings.

ANSWER:

18. Admit that NECC failed to submit a copy of the Mass. BoP's May 24, 2011 inspection report to the Tennessee Board of Pharmacy.

ANSWER:

19. Admit that you NECC owed a duty to its customers to ensure that its MPA was sterile prior to distributing it.

ANSWER:

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio
C.J. Gideon, Jr.*
Chris J. Tardio*
Alan S. Bean**
Matthew H. Cline*
315 Deaderick Street, Suite
Nashville, TN 37238
Ph: (615) 254-0400
Fax: (515) 254-0459
chris@gideoncooper.com

Attorneys for the Tennessee Clinic Defendants

* Admitted pursuant to MDL Order No. 1.
** Admitted *pro hac vice*.

CERTIFICATE OF SERVICE

I hereby certify that on the 31st day of March, 2015, a true and accurate copy of the foregoing was served on Carla Conigliaro by U.S. mail and on the other parties below electronically via the Court's CM/ECF system:

Gerard Stranch, IV Ben Gastel Branstetter, Stranch & Jennings, PLLC 227 2nd Ave N Suite 400 Nashville, TN 37201 *Attorneys for the PSC* [via hand-delivery, to upload to repository]	Matthew P. Moriarty Thomas W. Coffey Richard A. Dean Tucker Ellis, LLP 950 Main Avenue, Suite 1100 Cleveland, OH 44113 Scott H. Kremer Tucker, Heifetz & Saltzman Three School Street Boston, MA 02108 Scott J. Tucker Paul Saltzman Matthew E. Mantalos Tucker, Saltzman & Dyer, LLP 50 Congress Street Boston, MA 02109 *Attorneys for Defendant Ameridose, LLC*
Daniel M. Rabinovitz Brady J. Hermann Nicki Samson Michaels, Ward & Rabinovitz One Beacon Street , 2nd Floor Boston, MA 02108 *Attorneys for Defendant Medical Sales Management, Inc.*	John P. Ryan Robert H. Gaynor William J. Dailey, Jr. Sloane and Walsh, LLP Three Center Plaza Boston, MA 02108 *Attorneys for Gregory Conigliaro, Registered Agent for Service of Process for Medical Sales Management SW, Inc.*

Joseph P. Thomas Ulmer & Berne, LLP 600 Vine Street, Suite 2800 Cincinnati, OH 45202 Joshua A. Klarfeld Ulmer & Berne, LLP 1660 W.2nd Street, Suite 1100 Cleveland, OH 44113 *Attorneys for Defendant* *GDC Properties Management, LLC*	Kenneth B. Walton Kristen R. Ragosta Donovan Hatem, LLP Two Seaport Lane, 8th Floor Boston, MA 02210 *Attorneys for Defendant* *ARL Bio Pharma*
John P. Ryan Robert H. Gaynor William J. Dailey, Jr. Sloane and Walsh, LLP Three Center Plaza Boston, MA 02108 *Attorneys for Defendants Barry J. Cadden, Lisa Conigliaro Cadden, Gregory Conigliaro, Carla Conigliaro, Douglas Conigliaro and Glenn A. Chin* Bruce A. Singal Michelle R. Peirce Callan G. Stein Donague, Barrett & Singal, P.C. One Beacon Street , Suite 1320 Boston, MA 02108 *Attorneys for Defendants Barry J. Cadden and Lisa Conigliaro Cadden*	Damian W. Wilmot James Rehnquist Abigail K. Hemani Roberto M. Braceras Goodwin Procter LLP Exchange Place 53 State Street Boston, MA 02109 *Attorneys for Unifirst Corporation a/d/b/a Uniclean Cleanroom Services* Parks Chastain Jason Lee Brewer, Krause, Brooks, Chastain & Burrow, PLLC 611 Commerce St., Suite 2600 P.O. Box 23890 Nashville, TN 37202 615-256-8787 Fax: 615-256-8985 *Attorneys for Specialty Surgery Center, Crossville, PLLC*

Frederick H. Fern Judi Abbott Curry Jessica Saunders Eichel Alan M. Winchester Harris Beach PLLC 100 Wall Street 23rd Floor New York, NY 10005 Geoffrey M. Coan Daniel E. Tranen Hinshaw & Culbertson LLP 28 State Street 24th Floor Boston, MA 02109 Michael R. Gottfried Thomas B.K. Ringe, III Jennifer Mikels Duane Morris LLP 100 High Street Suite 2400 Boston, MA 02110-1724 *Attorneys for NECC*	Marcy H. Greer Alexander Dubose Jefferson & Townsent 515 Congress Ave. Suite 2350 Austin, TX 78701 Yvonne K. Puig Eric Hoffman Fulbright & Jaworski L.L.P. 98 San Jacinto Blvd. Suite 1100 Austin, TX 78701 Sarah P. Kelly Nutter, McClennen & Fish, LLP Seaport West 155 Seaport Boulevard Boston, MA 02210-2604 *Attorneys for the Saint Thomas Entities*

/s/ Chris J. Tardio
Chris J. Tardio

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	MDL No. 2419 Dkt. No. 1:13-md-2419-RWZ
This Document Relates to Suits Naming:	)	
Suits Naming the Tennessee Clinic Defendants	)	

THE TENNESSEE CLINIC DEFENDANTS' FIRST INTERROGATORIES, REQUESTS FOR PRODUCTON OF DOCUMENTS, AND REQUESTS FOR ADMISSION PROPOUNDED TO DOUGLAS CONIGLIARO.

Come the Defendants, Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants") , pursuant to Rules 26, 33, and 34 of the Federal Rules of Civil Procedure and the Local Rules for the District of Massachusetts, and propound the following Interrogatories, Requests for Production of Documents, and Requests for Admission to Douglas Conigliaro.

Each of the following Interrogatories shall be answered under oath, in writing, separately, to the fullest possible detail, and in accordance with the definitions and instructions set forth below. The answers shall be signed by the person making them, and a copy of the answers, together with objections, if any, shall be served within thirty (30) days after the service date of these Interrogatories.

You are under a duty to seasonably supplement your response with respect to any Interrogatory directly addressed to the identity and location of persons having knowledge of discoverable matters. You are under a duty to amend a prior response if you obtain information on the basis of which you know that the response was incorrect when made, or that the response, though correctly made, is no longer true, and the circumstances are such that a failure to amend the response is, in substance, a knowing concealment.

DEFINITIONS

1. As used in this document, the terms "person(s)" and "individual(s)" mean any natural individual in any capacity whatsoever or any entity or organization, including divisions, departments, and other units therein, and shall include, but not be limited to, a public or private corporation, partnership, joint venture, voluntary or unincorporated association, organization, proprietorship, trust, estate, governmental agency, commission, bureau, or department.

2. As used in this document, the term "document" means any medium upon which intelligence or information can be recorded or retrieved, and includes without limitation, the original and each copy, regardless of origin and location, of any book, pamphlet, periodical, letter, memorandum (including any memorandum or report of a meeting or conversation), invoice, bill, order form, receipt, financial statement, accounting entry, diary, calendar, telex, telegram, cable, report, record, contract, agreement, study, handwritten note, draft, working paper, chart, paper, print, laboratory record, drawing or sketch, graph, index, lists, tape, photograph, microfilm, data sheet or data processing card, or any other written, recorded, transcribed, punched, taped, filmed, or graphic matter, however produced or reproduced, which is in your possession, custody, or control, or which was, but is no longer, in your possession, custody, or control.

3. As used in this document, the terms "identification," "identify," or "identity," when used in reference to a natural individual, require you to state his or her full name and residential and business address. Use of the term "document" in connection with the Interrogatories requires you to state the number of pages and the nature of the document, its title, its date, the name or names of its authors, and recipients, and its present location and custodian.

4. "You" and "your" refers to Douglas Conigliaro and each of his present and former agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on his behalf.

5. "Communication" means any oral or written utterance, notification, or statement of any nature whatsoever, by and to whomsoever made, including, but not limited to, correspondence, conversation, dialogue, discussions, interviews, consultants, and any other understanding between or among two or more persons.

INSTRUCTIONS

1. With respect to each Interrogatory, in addition to answering the question, you are to identify all documents that support, refer to, or evidence the subject matter of each Interrogatory and your answer thereto.

   If any or all identified documents are no longer in your possession, custody, or control because of destruction, loss, or any other reason, then you must do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and the copy of the document;

   D. State in as much detail as possible the contents of the documents; and

   E. State the manner and date of disposition of the document.

   If you contend that you are entitled to withhold from production any or all documents identified herein on the basis of attorney-client privilege, the work-product doctrine, or any other ground, then do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and a copy of the document;

   D. State the subject matter of the document; and

   E. State the basis upon which you contend you are entitled to withhold the document from production.

2. All documents produced should be organized and labeled to correspond to the specific Request in response to which they are being made available or should be produced as they are kept in the usual course of business.

3. The terms "and," "or," and "and/or" should be construed either disjunctively or conjunctively so as to bring within the scope of these Interrogatories and Requests any information that might otherwise be construed as outside their scope.

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5. The present tense should be construed to include the past tense, and the past tense should be construed to include the present tense.

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INTERROGATORIES

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1-6. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Interrogatories 1-11 from the *Saint Thomas Entities' First Set of Interrogatories.*]

ANSWER:

7. Describe in detail your role at NECC and Ameridose, including job title, job description, and a description of your daily duties and activities in 2011 and 2012.

ANSWER:

8. Describe in detail the steps NECC took to compound, process, stopper, seal, package, and ship methylprednisolone acetate ("MPA") in 2011 and 2012, including but not limited to:

a) The names of the individuals performing each step;

b) The job titles for the individuals performing each step;

c) The specific cleanroom or location in NECC's facility where each step took place;

d) The tools, equipment, or machinery used for each step;

e) Any changes to NECC's methods and procedures for compounding MPA, or the location where compounding MPA took place, that occurred in 2011 or 2012.

ANSWER:

9. Identify the total amount of MPA that NECC, and separately Ameridose, produced in each quarter of 2010, 2011, and 2012.

ANSWER:

10. Identify the types of vials and closures NECC used for MPA lots numbered 052122012@68, 06292012@26, and 08102012@51 (collectively "Contaminated Lots"), including whether the vials and enclosures were prewashed or presterilized, and identify their manufacturer(s).

ANSWER:

11. Identify any and all complaints that NECC and Ameridose received related to the sterility or safety of their products, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER:

12. Identify any customers of NECC and Ameridose who performed site visits prior to placing orders with either company.

ANSWER:

13. Describe any policies, procedures, or protocols relating to or regarding customer site visits to the NECC facility, including the areas you allowed customers to inspect.

ANSWER:

14. Identify any customers who asked for information about prior recalls of NECC and Ameridose products prior to placing orders with either company.

ANSWER:

15. Identify and describe any information you gave customers about recalled NECC and Ameridose products in 2011 and 2012.

ANSWER:

16. Identify any and all complaints NECC or Ameridose received related to their compliance with state or federal laws and regulations, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER:

17. Identify and describe any way in which NECC's cleanrooms were modified, altered, or expanded by NECC or Ameridose.

ANSWER:

18. Identify any policies, procedures, or guidelines in place at NECC in 2012 that encouraged employees to disclose mistakes in the compounding process, even if the mistakes necessitated destruction of product or halting production.

ANSWER:

19. Describe all disciplinary or enforcement action taken against NECC or Ameridose by any state or federal government agency.

ANSWER:

20. Describe in detail Lisa Conigliaro Cadden's role at NECC in 2011 and 2012.

ANSWER:

VERIFICATION

STATE OF TENNESSEE)
)
COUNTY OF _____)

I, _____, after being duly sworn, hereby make oath that the foregoing answers to interrogatories are true to the best of my knowledge, information, and belief.

_____

Sworn to and subscribed before me this _____ day of _____, 2015.

_____
Notary Public

My commission expires on: _____.

REQUESTS FOR PRODUCTION

On March 19, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to Douglas Conigliaro.* In order to minimize the impact of discovery on Douglas Conigliaro, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Requests for Production 1-38** from the *Saint Thomas Entities' First Requests for Production.* The "new" requests begin at Number 39.

1-38. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Requests for Production 1-38 from the *Saint Thomas Entities' First Requests for Production.*]

RESPONSE:

39. Produce all correspondence between you and any of the Tennessee Clinic Defendants, their employees, agents, or representatives.

RESPONSE:

40. Produce all correspondence and documents referring or relating to the Tennessee Clinic Defendants' purchase of MPA from NECC in 2012.

RESPONSE:

41. Produce all documents produced by the government to you during any civil, criminal, and administrative proceedings related to NECC's contaminated MPA.

RESPONSE:

42. Produce all policies, procedures, guidelines, instructions and training documents referring or relating to the compounding of MPA at the NECC facility.

RESPONSE:

43. Produce all documents referring or relating to NECC or Ameridose sending samples of insufficient size or volume to comply with USP 71 to ARL or any other testing laboratory.

RESPONSE:

44. Produce all documents referring or relating to any sterility, potency, endotoxin, or fungal testing that you received from ARL or any other laboratory related to MPA compounded by NECC or Ameridose in 2011 and 2012.

RESPONSE:

45. Produce all correspondence and documents referring or relating to fungal blooms or growth in or near NECC's cleanrooms.

RESPONSE:

46. Produce documents referring or relating to complaints or communications with Liberty regarding the design, manufacture, or installation of the clean rooms at the NECC facility.

RESPONSE:

47. Produce all documents referring or relating to any complaints that NECC or Ameridose received related to the sterility or safety of their products, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

48. Produce all documents referring or relating to any complaints NECC or Ameridose received related to their compliance with state or federal laws and regulations, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

49. Produce all correspondence and documents referring or relating to NECC's response to the meningitis outbreak, including but not limited to, steps NECC took to prepare for any inspections of its facility.

RESPONSE:

50. Produce all training and instructional material for sales staff at NECC or MSM.

RESPONSE:

REQUESTS FOR ADMISSION

On March 19, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to Douglas Conigliaro.* In order to minimize the impact of discovery on Douglas Conigliaro, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Requests for Admission 1-10** from the *Saint Thomas Entities' First Requests for Admission.* The "new" requests begin at Number 11.

1-10. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Requests for Admission 1-10 from the *Saint Thomas Entities' First Requests for Admission*.]

ANSWER:

11. Admit that, had any of the Tennessee Clinic Defendants asked for a copy of NECC's license in 2011, you would have provided a valid and up-to-date Tennessee pharmacy license.

ANSWER:

12. Admit that NECC represented to its customers, including the Tennessee Clinic Defendants, that it met or exceeded USP 797 standards.

ANSWER:

13. Admit that NECC represented its customers, including the Tennessee Clinic Defendants, that its products, including MPA, were safe and sterile.

ANSWER:

14. Admit that the Massachusetts Board of Pharmacy ("Mass. BoP") inspected NECC on or about May 24, 2011.

ANSWER:

15. Admit that as a result of its inspection on or about May 24, 2011 the Mass. BoP issued an inspection report documenting its findings.

ANSWER:

16. Admit that NECC failed to submit a copy of the Mass. BoP's May 24, 2011 inspection report to the Tennessee Board of Pharmacy.

ANSWER:

17. Admit that you NECC had a duty to ensure that its MPA was sterile prior to distributing it to customers.

ANSWER:

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio
C.J. Gideon, Jr.*
Chris J. Tardio*
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Attorneys for the Tennessee Clinic Defendants

* Admitted pursuant to MDL Order No. 1.
** Admitted *pro hac vice*.

CERTIFICATE OF SERVICE

I hereby certify that on the 31st day of March, 2015, a true and accurate copy of the foregoing was served on Douglas Conigliaro by U.S. mail and on the other parties below electronically via the Court's CM/ECF system:

Gerard Stranch, IV Ben Gastel Branstetter, Stranch & Jennings, PLLC 227 2nd Ave N Suite 400 Nashville, TN 37201 *Attorneys for the PSC* [via hand-delivery, to upload to repository]	Matthew P. Moriarty Thomas W. Coffey Richard A. Dean Tucker Ellis, LLP 950 Main Avenue, Suite 1100 Cleveland, OH 44113 Scott H. Kremer Tucker, Heifetz & Saltzman Three School Street Boston, MA 02108 Scott J. Tucker Paul Saltzman Matthew E. Mantalos Tucker, Saltzman & Dyer, LLP 50 Congress Street Boston, MA 02109 *Attorneys for Defendant Ameridose, LLC*
Daniel M. Rabinovitz Brady J. Hermann Nicki Samson Michaels, Ward & Rabinovitz One Beacon Street , 2nd Floor Boston, MA 02108 *Attorneys for Defendant Medical Sales Management, Inc.*	John P. Ryan Robert H. Gaynor William J. Dailey, Jr. Sloane and Walsh, LLP Three Center Plaza Boston, MA 02108 *Attorneys for Gregory Conigliaro, Registered Agent for Service of Process for Medical Sales Management SW, Inc.*

Joseph P. Thomas Ulmer & Berne, LLP 600 Vine Street, Suite 2800 Cincinnati, OH 45202 Joshua A. Klarfeld Ulmer & Berne, LLP 1660 W.2nd Street, Suite 1100 Cleveland, OH 44113 *Attorneys for Defendant* *GDC Properties Management, LLC*	Kenneth B. Walton Kristen R. Ragosta Donovan Hatem, LLP Two Seaport Lane, 8th Floor Boston, MA 02210 *Attorneys for Defendant* *ARL Bio Pharma*
John P. Ryan Robert H. Gaynor William J. Dailey, Jr. Sloane and Walsh, LLP Three Center Plaza Boston, MA 02108 *Attorneys for Defendants Barry J. Cadden, Lisa Conigliaro Cadden, Gregory Conigliaro, Carla Conigliaro, Douglas Conigliaro and Glenn A. Chin* Bruce A. Singal Michelle R. Peirce Callan G. Stein Donague, Barrett & Singal, P.C. One Beacon Street , Suite 1320 Boston, MA 02108 *Attorneys for Defendants Barry J. Cadden and Lisa Conigliaro Cadden*	Damian W. Wilmot James Rehnquist Abigail K. Hemani Roberto M. Braceras Goodwin Procter LLP Exchange Place 53 State Street Boston, MA 02109 *Attorneys for Unifirst Corporation a/d/b/a Uniclean Cleanroom Services* Parks Chastain Jason Lee Brewer, Krause, Brooks, Chastain & Burrow, PLLC 611 Commerce St., Suite 2600 P.O. Box 23890 Nashville, TN 37202 615-256-8787 Fax: 615-256-8985 *Attorneys for Specialty Surgery Center, Crossville, PLLC*

Frederick H. Fern Judi Abbott Curry Jessica Saunders Eichel Alan M. Winchester Harris Beach PLLC 100 Wall Street 23rd Floor New York, NY 10005 Geoffrey M. Coan Daniel E. Tranen Hinshaw & Culbertson LLP 28 State Street 24th Floor Boston, MA 02109 Michael R. Gottfried Thomas B.K. Ringe, III Jennifer Mikels Duane Morris LLP 100 High Street Suite 2400 Boston, MA 02110-1724 *Attorneys for NECC*	Marcy H. Greer Alexander Dubose Jefferson & Townsent 515 Congress Ave. Suite 2350 Austin, TX 78701 Yvonne K. Puig Eric Hoffman Fulbright & Jaworski L.L.P. 98 San Jacinto Blvd. Suite 1100 Austin, TX 78701 Sarah P. Kelly Nutter, McClennen & Fish, LLP Seaport West 155 Seaport Boulevard Boston, MA 02210-2604 *Attorneys for the Saint Thomas Entities*

/s/ Chris J. Tardio
Chris J. Tardio

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	MDL No. 2419 Dkt. No. 1:13-md-2419-RWZ
This Document Relates to Suits Naming:	)	
Suits Naming the Tennessee Clinic Defendants	)	

THE TENNESSEE CLINIC DEFENDANTS' FIRST INTERROGATORIES, REQUESTS FOR PRODUCTON OF DOCUMENTS, AND REQUESTS FOR ADMISSION PROPOUNDED TO GREGORY CONIGLIARO.

Come the Defendants, Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants") , pursuant to Rules 26, 33, and 34 of the Federal Rules of Civil Procedure and the Local Rules for the District of Massachusetts, and propound the following Interrogatories, Requests for Production of Documents, and Requests for Admission to Gregory Conigliaro.

Each of the following Interrogatories shall be answered under oath, in writing, separately, to the fullest possible detail, and in accordance with the definitions and instructions set forth below. The answers shall be signed by the person making them, and a copy of the answers, together with objections, if any, shall be served within thirty (30) days after the service date of these Interrogatories.

You are under a duty to seasonably supplement your response with respect to any Interrogatory directly addressed to the identity and location of persons having knowledge of discoverable matters. You are under a duty to amend a prior response if you obtain information on the basis of which you know that the response was incorrect when made, or that the response, though correctly made, is no longer true, and the circumstances are such that a failure to amend the response is, in substance, a knowing concealment.

DEFINITIONS

1. As used in this document, the terms "person(s)" and "individual(s)" mean any natural individual in any capacity whatsoever or any entity or organization, including divisions, departments, and other units therein, and shall include, but not be limited to, a public or private corporation, partnership, joint venture, voluntary or unincorporated association, organization, proprietorship, trust, estate, governmental agency, commission, bureau, or department.

2. As used in this document, the term "document" means any medium upon which intelligence or information can be recorded or retrieved, and includes without limitation, the original and each copy, regardless of origin and location, of any book, pamphlet, periodical, letter, memorandum (including any memorandum or report of a meeting or conversation), invoice, bill, order form, receipt, financial statement, accounting entry, diary, calendar, telex, telegram, cable, report, record, contract, agreement, study, handwritten note, draft, working paper, chart, paper, print, laboratory record, drawing or sketch, graph, index, lists, tape, photograph, microfilm, data sheet or data processing card, or any other written, recorded, transcribed, punched, taped, filmed, or graphic matter, however produced or reproduced, which is in your possession, custody, or control, or which was, but is no longer, in your possession, custody, or control.

3. As used in this document, the terms "identification," "identify," or "identity," when used in reference to a natural individual, require you to state his or her full name and residential and business address. Use of the term "document" in connection with the Interrogatories requires you to state the number of pages and the nature of the document, its title, its date, the name or names of its authors, and recipients, and its present location and custodian.

4. "You" and "your" refers to Gregory Conigliaro and each of his present and former agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on his behalf.

5. "Communication" means any oral or written utterance, notification, or statement of any nature whatsoever, by and to whomsoever made, including, but not limited to, correspondence, conversation, dialogue, discussions, interviews, consultants, and any other understanding between or among two or more persons.

INSTRUCTIONS

1. With respect to each Interrogatory, in addition to answering the question, you are to identify all documents that support, refer to, or evidence the subject matter of each Interrogatory and your answer thereto.

   If any or all identified documents are no longer in your possession, custody, or control because of destruction, loss, or any other reason, then you must do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and the copy of the document;

   D. State in as much detail as possible the contents of the documents; and

   E. State the manner and date of disposition of the document.

   If you contend that you are entitled to withhold from production any or all documents identified herein on the basis of attorney-client privilege, the work-product doctrine, or any other ground, then do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and a copy of the document;

   D. State the subject matter of the document; and

   E. State the basis upon which you contend you are entitled to withhold the document from production.

2. All documents produced should be organized and labeled to correspond to the specific Request in response to which they are being made available or should be produced as they are kept in the usual course of business.

3. The terms "and," "or," and "and/or" should be construed either disjunctively or conjunctively so as to bring within the scope of these Interrogatories and Requests any information that might otherwise be construed as outside their scope.

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7. Describe in detail your role at NECC and Ameridose, including job title, job description, and a description of your daily duties and activities in 2011 and 2012.

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a) The names of the individuals performing each step;

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e) Any changes to NECC's methods and procedures for compounding MPA, or the location where compounding MPA took place, that occurred in 2011 or 2012.

ANSWER:

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ANSWER:

18. Identify any policies, procedures, or guidelines in place at NECC in 2012 that encouraged employees to disclose mistakes in the compounding process, even if the mistakes necessitated destruction of product or halting production.

ANSWER:

19. Describe all disciplinary or enforcement action taken against NECC or Ameridose by any state or federal government agency.

ANSWER:

20. Describe in detail Lisa Conigliaro Cadden's role at NECC in 2011 and 2012.

ANSWER:

VERIFICATION

STATE OF TENNESSEE)
)
COUNTY OF _____)

I, _____, after being duly sworn, hereby make oath that the foregoing answers to interrogatories are true to the best of my knowledge, information, and belief.

_____

Sworn to and subscribed before me this _____ day of _____, 2015.

_____
Notary Public

My commission expires on: _____.

REQUESTS FOR PRODUCTION

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1-38. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Requests for Production 1-38 from the *Saint Thomas Entities' First Requests for Production.*]

RESPONSE:

39. Produce all correspondence between you and any of the Tennessee Clinic Defendants, their employees, agents, or representatives.

RESPONSE:

40. Produce all correspondence and documents referring or relating to the Tennessee Clinic Defendants' purchase of MPA from NECC in 2012.

RESPONSE:

41. Produce all documents produced by the government to you during any civil, criminal, or administrative proceedings related to NECC's contaminated MPA.

RESPONSE:

42. Produce all policies, procedures, guidelines, instructions and training documents referring or relating to the compounding of MPA at the NECC facility.

RESPONSE:

43. Produce all documents referring or relating to NECC or Ameridose sending samples of insufficient size or volume to comply with USP 71 to ARL or any other testing laboratory.

RESPONSE:

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RESPONSE:

45. Produce all correspondence and documents referring or relating to fungal blooms or growth in or near NECC's cleanrooms.

RESPONSE:

46. Produce documents referring or relating to complaints or communications with Liberty regarding the design, manufacture, or installation of the clean rooms at the NECC facility.

RESPONSE:

47. Produce all documents referring or relating to any complaints that NECC or Ameridose received related to the sterility or safety of their products, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

48. Produce all documents referring or relating to any complaints NECC or Ameridose received related to their compliance with state or federal laws and regulations, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

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RESPONSE:

50. Produce all training and instructional material for sales staff at NECC or MSM.

RESPONSE:

REQUESTS FOR ADMISSION

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1-19. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Requests for Admission 1-19 from the *Saint Thomas Entities' First Requests for Admission.*]

ANSWER:

20. Admit that, had any of the Tennessee Clinic Defendants asked for a copy of NECC's license in 2011, you would have provided a valid and up-to-date Tennessee pharmacy license.

ANSWER:

21. Admit that NECC represented to its customers, including the Tennessee Clinic Defendants, that it met or exceeded USP 797 standards.

ANSWER:

22. Admit that NECC represented to its customers, including the Tennessee Clinic Defendants, that its products, including MPA, were safe and sterile.

ANSWER:

23. Admit that the Massachusetts Board of Pharmacy ("Mass. BoP") inspected NECC on or about May 24, 2011.

ANSWER:

24. Admit that as a result of its inspection on or about May 24, 2011 the Mass. BoP issued an inspection report documenting its findings.

ANSWER:

25. Admit that NECC failed to submit a copy of the Mass. BoP's May 24, 2011 inspection report to the Tennessee Board of Pharmacy.

ANSWER:

26. Admit that you NECC owed a duty to its customers to ensure that its MPA was sterile prior to distributing it.

ANSWER:

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio
C.J. Gideon, Jr.*
Chris J. Tardio*
Alan S. Bean**
Matthew H. Cline*
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chris@gideoncooper.com

Attorneys for the Tennessee Clinic Defendants

* Admitted pursuant to MDL Order No. 1.
** Admitted *pro hac vice*.

CERTIFICATE OF SERVICE

I hereby certify that on the 31st day of March, 2015, a true and accurate copy of the foregoing was served on Gregory Conigliaro by U.S. mail and on the other parties below electronically via the Court's CM/ECF system:

Gerard Stranch, IV Ben Gastel Branstetter, Stranch & Jennings, PLLC 227 2nd Ave N Suite 400 Nashville, TN 37201 *Attorneys for the PSC* [via hand-delivery, to upload to repository]	Matthew P. Moriarty Thomas W. Coffey Richard A. Dean Tucker Ellis, LLP 950 Main Avenue, Suite 1100 Cleveland, OH 44113 Scott H. Kremer Tucker, Heifetz & Saltzman Three School Street Boston, MA 02108 Scott J. Tucker Paul Saltzman Matthew E. Mantalos Tucker, Saltzman & Dyer, LLP 50 Congress Street Boston, MA 02109 *Attorneys for Defendant Ameridose, LLC*
Daniel M. Rabinovitz Brady J. Hermann Nicki Samson Michaels, Ward & Rabinovitz One Beacon Street , 2nd Floor Boston, MA 02108 *Attorneys for Defendant Medical Sales Management, Inc.*	John P. Ryan Robert H. Gaynor William J. Dailey, Jr. Sloane and Walsh, LLP Three Center Plaza Boston, MA 02108 *Attorneys for Gregory Conigliaro, Registered Agent for Service of Process for Medical Sales Management SW, Inc.*

Joseph P. Thomas Ulmer & Berne, LLP 600 Vine Street, Suite 2800 Cincinnati, OH 45202 Joshua A. Klarfeld Ulmer & Berne, LLP 1660 W.2nd Street, Suite 1100 Cleveland, OH 44113 *Attorneys for Defendant* *GDC Properties Management, LLC*	Kenneth B. Walton Kristen R. Ragosta Donovan Hatem, LLP Two Seaport Lane, 8th Floor Boston, MA 02210 *Attorneys for Defendant* *ARL Bio Pharma*
John P. Ryan Robert H. Gaynor William J. Dailey, Jr. Sloane and Walsh, LLP Three Center Plaza Boston, MA 02108 *Attorneys for Defendants Barry J. Cadden, Lisa Conigliaro Cadden, Gregory Conigliaro, Carla Conigliaro, Douglas Conigliaro and Glenn A. Chin* Bruce A. Singal Michelle R. Peirce Callan G. Stein Donague, Barrett & Singal, P.C. One Beacon Street , Suite 1320 Boston, MA 02108 *Attorneys for Defendants Barry J. Cadden and Lisa Conigliaro Cadden*	Damian W. Wilmot James Rehnquist Abigail K. Hemani Roberto M. Braceras Goodwin Procter LLP Exchange Place 53 State Street Boston, MA 02109 *Attorneys for Unifirst Corporation a/d/b/a Uniclean Cleanroom Services* Parks Chastain Jason Lee Brewer, Krause, Brooks, Chastain & Burrow, PLLC 611 Commerce St., Suite 2600 P.O. Box 23890 Nashville, TN 37202 615-256-8787 Fax: 615-256-8985 *Attorneys for Specialty Surgery Center, Crossville, PLLC*

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/s/ Chris J. Tardio
Chris J. Tardio

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	MDL No. 2419 Dkt. No. 1:13-md-2419-RWZ
This Document Relates to Suits Naming:	)	
Suits Naming the Tennessee Clinic Defendants	)	

THE TENNESSEE CLINIC DEFENDANTS' FIRST INTERROGATORIES, REQUESTS FOR PRODUCTON OF DOCUMENTS, AND REQUESTS FOR ADMISSION PROPOUNDED TO LISA CONIGLIARO CADDEN.

Come the Defendants, Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants") , pursuant to Rules 26, 33, and 34 of the Federal Rules of Civil Procedure and the Local Rules for the District of Massachusetts, and propound the following Interrogatories, Requests for Production of Documents, and Requests for Admission to Lisa Conigliaro Cadden.

Each of the following Interrogatories shall be answered under oath, in writing, separately, to the fullest possible detail, and in accordance with the definitions and instructions set forth below. The answers shall be signed by the person making them, and a copy of the answers, together with objections, if any, shall be served within thirty (30) days after the service date of these Interrogatories.

You are under a duty to seasonably supplement your response with respect to any Interrogatory directly addressed to the identity and location of persons having knowledge of discoverable matters. You are under a duty to amend a prior response if you obtain information on the basis of which you know that the response was incorrect when made, or that the response, though correctly made, is no longer true, and the circumstances are such that a failure to amend the response is, in substance, a knowing concealment.

DEFINITIONS

1. As used in this document, the terms "person(s)" and "individual(s)" mean any natural individual in any capacity whatsoever or any entity or organization, including divisions, departments, and other units therein, and shall include, but not be limited to, a public or private corporation, partnership, joint venture, voluntary or unincorporated association, organization, proprietorship, trust, estate, governmental agency, commission, bureau, or department.

2. As used in this document, the term "document" means any medium upon which intelligence or information can be recorded or retrieved, and includes without limitation, the original and each copy, regardless of origin and location, of any book, pamphlet, periodical, letter, memorandum (including any memorandum or report of a meeting or conversation), invoice, bill, order form, receipt, financial statement, accounting entry, diary, calendar, telex, telegram, cable, report, record, contract, agreement, study, handwritten note, draft, working paper, chart, paper, print, laboratory record, drawing or sketch, graph, index, lists, tape, photograph, microfilm, data sheet or data processing card, or any other written, recorded, transcribed, punched, taped, filmed, or graphic matter, however produced or reproduced, which is in your possession, custody, or control, or which was, but is no longer, in your possession, custody, or control.

3. As used in this document, the terms "identification," "identify," or "identity," when used in reference to a natural individual, require you to state his or her full name and residential and business address. Use of the term "document" in connection with the Interrogatories requires you to state the number of pages and the nature of the document, its title, its date, the name or names of its authors, and recipients, and its present location and custodian.

4. "You" and "your" refers to Lisa Conigliaro Cadden and each of his present and former agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on his behalf.

5. "Communication" means any oral or written utterance, notification, or statement of any nature whatsoever, by and to whomsoever made, including, but not limited to, correspondence, conversation, dialogue, discussions, interviews, consultants, and any other understanding between or among two or more persons.

INSTRUCTIONS

1. With respect to each Interrogatory, in addition to answering the question, you are to identify all documents that support, refer to, or evidence the subject matter of each Interrogatory and your answer thereto.

   If any or all identified documents are no longer in your possession, custody, or control because of destruction, loss, or any other reason, then you must do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and the copy of the document;

   D. State in as much detail as possible the contents of the documents; and

   E. State the manner and date of disposition of the document.

   If you contend that you are entitled to withhold from production any or all documents identified herein on the basis of attorney-client privilege, the work-product doctrine, or any other ground, then do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and a copy of the document;

   D. State the subject matter of the document; and

   E. State the basis upon which you contend you are entitled to withhold the document from production.

2. All documents produced should be organized and labeled to correspond to the specific Request in response to which they are being made available or should be produced as they are kept in the usual course of business.

3. The terms "and," "or," and "and/or" should be construed either disjunctively or conjunctively so as to bring within the scope of these Interrogatories and Requests any information that might otherwise be construed as outside their scope.

4. The term "any" should be construed to include the word "all," and "all" should be construed to include "any."

5. The present tense should be construed to include the past tense, and the past tense should be construed to include the present tense.

6. The singular should be construed to include the plural, and the plural should be construed to include the singular.

7. The terms "he" and "his" should be construed to include the words "she" and "her" or "hers," respectively and vice versa.

8. "Relating to," when referring to a document shall mean mentioning, describing, connected to or with, or discussing the stated subject matter.

INTERROGATORIES

On March 19, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to Lisa Conigliaro Cadden.* In order to minimize the impact of discovery on Lisa Conigliaro Cadden, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Interrogatories 1-6** from the *Saint Thomas Entities' First Set of Interrogatories.*

1-6. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Interrogatories 1-11 from the *Saint Thomas Entities' First Set of Interrogatories.*]

ANSWER:

7. Describe in detail your role at NECC and Ameridose, including job title, job description, and a description of your daily duties and activities in 2011 and 2012.

ANSWER:

8. Describe in detail the steps NECC took to compound, process, stopper, seal, package, and ship methylprednisolone acetate ("MPA") in 2011 and 2012, including but not limited to:

a) The names of the individuals performing each step;

b) The job titles for the individuals performing each step;

c) The specific cleanroom or location in NECC's facility where each step took place;

d) The tools, equipment, or machinery used for each step;

e) Any changes to NECC's methods and procedures for compounding MPA, or the location where compounding MPA took place, that occurred in 2011 or 2012.

ANSWER:

9. Identify the total amount of MPA that NECC, and separately Ameridose, produced in each quarter of 2010, 2011, and 2012.

ANSWER:

10. Identify the types of vials and closures NECC used for MPA lots numbered 052122012@68, 06292012@26, and 08102012@51 (collectively "Contaminated Lots"), including whether the vials and enclosures were prewashed or presterilized, and identify their manufacturer(s).

ANSWER:

11. Identify any and all complaints that NECC and Ameridose received related to the sterility or safety of their products, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER:

12. Identify any customers of NECC and Ameridose who performed site visits prior to placing orders with either company.

ANSWER:

13. Describe any policies, procedures, or protocols relating to or regarding customer site visits to the NECC facility, including the areas you allowed customers to inspect.

ANSWER:

14. Identify any customers who asked for information about prior recalls of NECC and Ameridose products prior to placing orders with either company.

ANSWER:

15. Identify and describe any information you gave customers about recalled NECC and Ameridose products in 2011 and 2012.

ANSWER:

16. Identify any and all complaints NECC or Ameridose received related to their compliance with state or federal laws and regulations, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER:

17. Identify and describe any way in which NECC's cleanrooms were modified, altered, or expanded by NECC or Ameridose.

ANSWER:

18. Identify any policies, procedures, or guidelines in place at NECC in 2012 that encouraged employees to disclose mistakes in the compounding process, even if the mistakes necessitated destruction of product or halting production.

ANSWER:

19. Describe all disciplinary or enforcement action taken against NECC or Ameridose by any state or federal government agency.

ANSWER:

VERIFICATION

STATE OF TENNESSEE)
)
COUNTY OF _____)

I, _____, after being duly sworn, hereby make oath that the foregoing answers to interrogatories are true to the best of my knowledge, information, and belief.

_____

Sworn to and subscribed before me this _____ day of _____, 2015.

_____
Notary Public

My commission expires on: _____.

REQUESTS FOR PRODUCTION

On March 19, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to Lisa Conigliaro Cadden.* In order to minimize the impact of discovery on Lisa Conigliaro Cadden, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Requests for Production 1-39** from the *Saint Thomas Entities' First Requests for Production*. The "new" requests begin at Number 40.

1-39. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Requests for Production 1-39 from the *Saint Thomas Entities' First Requests for Production*.]

RESPONSE:

40. Produce all correspondence between you and any of the Tennessee Clinic Defendants, their employees, agents, or representatives.

RESPONSE:

41. Produce all correspondence and documents referring or relating to the Tennessee Clinic Defendants' purchase of MPA from NECC in 2012.

RESPONSE:

42. Produce all documents produced by the government to you during any civil, criminal, and administrative proceedings related to NECC's contaminated MPA.

RESPONSE:

43. Produce all policies, procedures, guidelines, instructions and training documents referring or relating to the compounding of MPA at the NECC facility.

RESPONSE:

44. Produce all documents referring or relating to NECC or Ameridose sending samples of insufficient size or volume to comply with USP 71 to ARL or any other testing laboratory.

RESPONSE:

45. Produce all documents referring or relating to any sterility, potency, endotoxin, or fungal testing that you received from ARL or any other laboratory related to MPA compounded by NECC or Ameridose in 2011 and 2012.

RESPONSE:

46. Produce all correspondence and documents referring or relating to fungal blooms or growth in or near NECC's cleanrooms.

RESPONSE:

47. Produce documents referring or relating to complaints or communications with Liberty regarding the design, manufacture, or installation of the clean rooms at the NECC facility.

RESPONSE:

48. Produce all documents referring or relating to any complaints that NECC or Ameridose received related to the sterility or safety of their products, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

49. Produce all documents referring or relating to any complaints NECC or Ameridose received related to their compliance with state or federal laws and regulations, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

50. Produce all correspondence and documents referring or relating to NECC's response to the meningitis outbreak, including but not limited to, steps NECC took to prepare for any inspections of its facility.

RESPONSE:

51. Produce all training and instructional material for sales staff at NECC or MSM.

RESPONSE:

REQUESTS FOR ADMISSION

On March 19, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to Lisa Conigliaro Cadden.* In order to minimize the impact of discovery on Lisa Conigliaro Cadden, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Requests for Admission 1-17** from the *Saint Thomas Entities' First Requests for Admission.* The "new" requests begin at Number 18.

1-17. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Requests for Admission 1-17 from the *Saint Thomas Entities' First Requests for Admission.*]

ANSWER:

18. Admit that, had any of the Tennessee Clinic Defendants asked for a copy of NECC's license in 2011, you would have provided a valid and up-to-date Tennessee pharmacy license.

ANSWER:

19. Admit that NECC represented to its customers, including the Tennessee Clinic Defendants, that it met or exceeded USP 797 standards.

ANSWER:

20. Admit that NECC represented to its customers, including the Tennessee Clinic Defendants, that its products, including MPA, were safe and sterile.

ANSWER:

21. Admit that the Massachusetts Board of Pharmacy ("Mass. BoP") inspected NECC on or about May 24, 2011.

ANSWER:

22. Admit that as a result of its inspection on or about May 24, 2011 the Mass. BoP issued an inspection report documenting its findings.

ANSWER:

23. Admit that NECC failed to submit a copy of the Mass. BoP's May 24, 2011 inspection report to the Tennessee Board of Pharmacy.

ANSWER:

24. Admit that you NECC owed a duty to its customers to ensure that its MPA was sterile prior to distributing it.

ANSWER:

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio
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Attorneys for the Tennessee Clinic Defendants

* Admitted pursuant to MDL Order No. 1.
** Admitted *pro hac vice*.

CERTIFICATE OF SERVICE

I hereby certify that on the 31st day of March, 2015, a true and accurate copy of the foregoing was served on Lisa Conigliaro Cadden by U.S. mail and on the other parties below electronically via the Court's CM/ECF system:

Gerard Stranch, IV Ben Gastel Branstetter, Stranch & Jennings, PLLC 227 2nd Ave N Suite 400 Nashville, TN 37201 *Attorneys for the PSC* [via hand-delivery, to upload to repository]	Matthew P. Moriarty Thomas W. Coffey Richard A. Dean Tucker Ellis, LLP 950 Main Avenue, Suite 1100 Cleveland, OH 44113 Scott H. Kremer Tucker, Heifetz & Saltzman Three School Street Boston, MA 02108 Scott J. Tucker Paul Saltzman Matthew E. Mantalos Tucker, Saltzman & Dyer, LLP 50 Congress Street Boston, MA 02109 *Attorneys for Defendant Ameridose, LLC*
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/s/ Chris J. Tardio
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